ARSENIC-CONTAMINATED SOILS

Questions and Discussion Materials

Prepared for the Science Advisory Board

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Introduction

In 1994, the Washington Legislature established the Model Toxics Control Act (MTCA) Policy Advisory Committee (PAC) to review implementation of MTCA. In their final report, the MTCA PAC recommended that Ecology take steps to more effectively address area-wide soil contamination. In early 2000, staff and managers from the Departments of Agriculture, Ecology, Health, and Community, Trade and Economic Development (Agencies) met several times to discuss this issue. The agencies identified several interconnected challenges posed by widespread low-to-moderate level soil contamination and concluded that effective, long-term solutions to area-wide soil contamination problems would require looking beyond traditional cleanup processes and agency boundaries.

The Agencies chartered the Area-Wide Soil Contamination Task Force (Task Force) in January 2002 to consider the special challenges posed by area-wide soil contamination and recommend a statewide strategy for meeting those challenges. The Task Force submitted their final report to the Agencies on June 30, 2003. The Task Force provided the Agencies with numerous recommendations including several that related to the implementation of MTCA. In particular, the Task Force recommended that Ecology use an approach to address properties or areas with "low-to-moderate" levels of lead and arsenic that is different than the one used for properties or areas found to have "high" levels of lead and arsenic.

The Task Force did not identify a range of concentrations they considered to be "low-to-moderate" or "high". However, concurrent with the Task Force deliberations, Ecology developed a working definition to support ongoing efforts to reduce the potential for children's exposure at schools, child care facilities and other land uses. The working definition has two parts:

- <u>Schools, childcare centers, and residential land uses</u>: The low-to-moderate range includes soils with average arsenic concentrations of <u>up to</u> 100 parts per million (ppm) and average lead concentrations of <u>up to</u> 500 – 700 ppm.
- <u>Commercial properties, parks, etc (i.e. properties where exposure of children is less likely or less frequent)</u>: The low-to-moderate range includes soils with average arsenic concentrations of up to 200 ppm and average lead concentrations of <u>up to</u> 700 – 1,000 ppm.

The Task Force briefly discussed the working definition and agreed with Ecology's plan to have the Science Advisory Board review the scientific and technical rationale for the concentration ranges reflected in the working definition.

The MTCA Science Advisory Board reviewed and provided recommendations on the working definition for lead-contaminated soils at several meetings in 2004. The Board also reviewed information on the toxicity of arsenic. The purpose of this document is to facilitate the Board's review of the methods and assumptions used by Ecology's to develop the working definition for arsenic-contaminated soils. The discussion materials are organized into three main sections:

- Summary of information on the range of arsenic concentrations in Washington soils;
- Summary of the information used by Ecology to characterize health risks associated with exposure to arsenic-contaminated soils; and
- A series of sections that identify questions for the Science Advisory Board, Ecology's assumptions and rationale for the approach used to address that issue, the Board's conclusions on the issue (based on previous discussions) and background information on each issue.

Arsenic Soil Concentrations in Washington

The Task Force considered two main sources of elevated levels of arsenic in soils: (1) past releases from smelters in Tacoma, Everett, Northport, Trail B.C. and Harbor Island; and (2) past use of lead arsenate pesticides. The following information on the range of soil arsenic concentrations summarizes information that was compiled by Landau Associates (2003a) during the Task Force process:

- Smelters: A wide range of arsenic concentrations have been measured in soils collected from areas around former smelters. Excluding the smelter properties and areas immediately adjacent to those properties (within 500 to 1000 ft), most of the arsenic contamination is present in the upper 12 - 24 inches. Arsenic concentrations in shallow soil samples ranged from natural background levels[1] to over 1000 mg/kg. The distribution of arsenic concentrations from several studies is shown in Tables 1 and 2. Sampling performed by Ecology, the Tacoma Pierce County Health Department and Public Health Seattle King County indicates that average arsenic concentrations at schools, child care facilities and parks are generally less than 40 mg/kg. In general, the highest concentrations have been found on or immediately adjacent to the smelter site with concentrations declining with increasing distance from the smelter site in the prevailing wind direction. In all cases, significant variability in the concentrations of arsenic was found in soils collected from these areas.

- Lead arsenate pesticides: Lead arsenate was the primary arsenical pesticide[2] used in Washington from the early 1900s until about 1947 when it was replaced by other pesticides such as DDT. Studies completed by Washington State University (WSU) of shallow orchard soils indicate residual arsenic concentrations range from background levels to concentrations up to 1,000 mg/kg (Peryea and Creger, 1994). Similar concentrations have been found during environmental site investigations of former orchard lands being developed for residential or commercial use (Landau 2003a). Average concentrations for individual properties are typically much lower than the maximum concentration listed above. The distribution of arsenic concentrations from several studies is shown in Tables 1 and 2. Current studies indicate that most of the arsenic deposited in surface soils remains in the upper 12 – 24 inches. For example, studies completed by WSU found that high concentrations of arsenic were limited to shallow soils (5 to 30 cm or 2 to 12 inch depth) and decreased sharply with depth. Most of the lead and arsenic was found in the upper 40 cm (16 inches) of soil. However, in some cases, the concentrations at the soil surface were lower than surface than concentrations found lower in the soil profile (suggesting downward movement and/or soil disturbance).

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[1] The 90th percentile values for natural background concentrations range from 7 to 9 mg/kg in different parts of the state (Ecology, 1994))

[2] Lead arsenate was typically used to control chewing insects. Though it was reportedly used on a wide variety of crops, its most extensive use was on apple and pear orchards to control the codling moth. Consequently, the highest accumulated concentrations of lead and arsenic in soil from historical lead arsenate use is expected to be in areas occupied by apple and pear orchards during the first half of the twentieth century. Lead arsenate was applied with increased frequency and in higher potency solutions during this time period because of the increasing resistance of the codling moth. Lead arsenate was used at far lower solution strengths with other crop types and was less frequently applied. Also other crop types changed more frequently relative to apple and pears. Consequently, metals soil concentrations are predicted to be highest associated with historical apple and pear cultivation relative to historical cultivation of other crops.

Table 1: Distribution of Arsenic Concentrations in Surface Soils Reported in Selected Studies

Area	Depth	N	Arsenic Concentrations (mg/kg) - Percentiles						% > MTCA (#)
			10%	25%	50%	75%	90%	MAX	
Everett Smelter Remedial Investigation/Feasibility Study									
< 100 ft	0-6”	12			344			2600	100% (12)
100 – 500 ft	0-6”	108	35	135	345	1400	3800	3800	93% (100)
500 – 1000 ft	0-6”	241	18	27	60	144	351	351	61% (146)
1000 – 2000 ft	0-6”	398	12	23	44	90	152	152	81% (323)
> 2000 ft	0-6”	232	6	16	18	23	36	36	37% (86)
Tacoma Smelter Plume Studies									
South Vashon (forests, etc.)	0-2”	81	37	41	67	120	160	360	--
Maury Island (forests, etc.)	0-2”	45	34	63	110	150	190	340	--
North Vashon (forests, etc)	0-2”	95	10	18	29	43	63	140	--
King County Mainland (“ ”)	0-2”	24	18	29	43	72	160	200	--
MVI Child Use Areas	0-2”	350	2	5	12	23	55	210	31% (107)
Pierce County Schools	0-2”	223	1	2	5	12	25	557	14% (31)
King County Schools	0-2”	542	3	4	7	12	19	133	9% (49)
Pierce County – Other CUA	0-2”	189	5	8	14	28	42	331	35% (66)
King County – Other CUA	0-2”	1000	4	5	9	13	18	47	8% (21)
University Place Homes	0-2”	100	8	15	25	36	48	113	59% (59)
Other Washington Studies									
Ecology Homeowner Study	0-2”	154	3	6	11	16	33	160	19% (29)
	12-18”	154	3	5	10	18	42	235	21% (33)
Manson Area Study	0-12”	815	6	18	47	90	135	1100	
Wenatchee Elem. Schools	0-2”	77	4	8	33	66	158	332	66% (51)
Wenatchee - Costco	0-24”	56	7	13	27	82	210	1800	
Yakima - Kissel Park	0-6”	91	23	31	45	63	74	85	93% (85)
	6-24”	88	16	23	34	51	66	95	82% (72)

Table 2: Comparison of Distribution of Average and Individual Arsenic Concentrations Found in Surface Soils Reported in Selected Studies (mg/kg)

Area	Depth	N	Arsenic Concentrations (mg/kg) - Percentiles						% > MTCA
			10%	25%	50%	75%	90%	MAX	
Maury/Vashon Island Child Use Areas									
Soil Samples	0-2”	350	2	5	12	23	55	210	31%(107)
Child Use Area Averages	0-6”	48	6	10	14	17	33	49	23% (11)
UCL on CUA Averages	0-6”	48	13	18	28	100	210	837	71% (34)
King County Schools									
Soil Samples	0-2”	542	3	4	7	12	19	133	9% (49)
Decision Unit Averages	0-2”	81	4	5	8	10	16	39	5% (4)
Pierce County Schools									
Soil Samples	0-2”	223	1	2	5	12	25	557	14% (31)
Decision Unit Averages	0-2”	28	2	4	8	14	27	91	14% (4)
Manson Area Study									
Soil Samples	0-12”	815	6	18	47	90	135	1100	
Tract Averages	0-12”	247	6	20	49	80	118	241	

Ecology and local health departments conduct two types of soil sampling studies. First, the agencies conduct studies that are designed to identify broad areas of concern. The information from these types of studies is used to prepare maps such as the maps showing arsenic and arsenic concentrations in areas around the former Asarco smelter. These studies are not designed to provide enough information to make property-specific decisions. Second, Ecology and local agencies conduct studies that are designed to evaluate soil concentrations at individual properties within these broader areas of concern. The following paragraphs provide two examples that illustrate (1) the variability in soil concentrations found at individual properties and (2) the sampling strategies being used to evaluate individual properties.

- Sampling Results for Child Play Areas in Western Washington: In late 1999, staff from Public Health - Seattle King County and the Department of Ecology collected soil samples from 48 child play areas at schools, child care facilities, parks and camps on Vashon and Maury Islands. Six to eight soil cores (24" in depth)[3] were collected from most play areas and soil from 5 depth intervals were analyzed for lead and arsenic. Arsenic concentrations ranged from non-detectable to 210 mg/kg with the highest concentrations reported in the two upper depth intervals (0-2" and 2-6"). MTCAStat was used to calculate the mean and upper 95th upper confidence limit on the mean (UCL95) for the upper two depth intervals at each of the 48 child play areas. The distribution of sample results, mean soil concentrations and UCL95 values for the 48 child play areas are shown in Table 2. Mean arsenic concentrations ranged from < 2 to 49 mg/kg. UCL95 values ranged from 6 to 837 mg/kg. Table 3 provides a comparison of the arithmetic mean, the standard deviation, UCL95 and maximum values for the 10 play areas with the highest mean arsenic concentrations. Table 4 illustrates the variations in soil concentrations measured in samples collected at two child play areas (e.g. playground and open space area) located at the same school property.

Table 3: Summary Statistics for the 10 Child Play Areas on Vashon & Maury Islands with the Highest Average Arsenic Levels

Decision Unit	MEAN	DIST	UCL95	Max
Site 1-28-2	49.0	None	131	131
Site 1-28-1	45.9	Lognormal	71	71
Site 2-22-1	43.5	Lognormal	837	110
Site 1-45-1	40.5	Lognormal	120	110
Site 2-22-1	38.7	None	130	130
Site 2-9-1	30.5	Normal	50	38
Site 1-27-1	30	Lognormal	176	69
Site 1-27-3	27.2	Lognormal	166	74
Site 1-39-1	24.1	Lognormal	322	86
Site 2-6-1	23.9	Lognormal	34	43

[3] Since the initial soil sampling, Health Department and Ecology staff have collected soil samples from two depth intervals (0-2" and 2-6") at schools and child care facilities in King and Pierce Counties.

Table 4: Arsenic Levels from Two Play Areas at One School		
Sample Location	Decision Unit 1	Decision Unit 2
1	70	27
2	25	25
3	40	31
4	58	26
5	47	130
6	71	100
7	19	32
8	37	21

- Sampling Results for Play Areas at Schools in Eastern Washington: In Spring 2002, Ecology staff collected soil samples from child play areas (e.g. playground, ball field, other open areas) at several schools in the Wenatchee area. Ecology collected 5-10 surface soil samples from each child play area and analyzed the samples for lead and arsenic. Arsenic concentrations ranged from non-detectable to 332 mg/kg. MTCAStat was used to calculate the arithmetic mean and upper 95th upper confidence limit on the mean (UCL95) for each school property. Mean arsenic concentrations for individual child play areas ranged from below detection limits to 160 mg/kg. UCL95 values ranged from 20 to 657 mg/kg. Table 5 provides a comparison of the arithmetic mean, the standard deviations, UCL95 and maximum values for the 10 play areas with the highest arsenic concentrations. The average concentrations at three child play areas exceeded 100 mg/kg. UCL95s for six of the ten play areas exceeded 100 mg/kg[4]. Table 6 provides the individual sample results for three of the ten child play areas with the highest average concentrations.

Table 5: Summary Statistics for the 10 Play Areas at Wenatchee Area Schools With the Highest Average Arsenic Concentrations					
Decision Unit	**N**	**MEAN**	**DIST**	**UCL95**	**Max**
#A	6	160	Lognormal	368	318
#B	7	142	Lognormal	657	332
#C	7	122	Lognormal	280	199
#D	10	82	Lognormal	94	100
#E	7	71	Lognormal	88	110
#F	7	50	Lognormal	112	78
#G	5	49	Lognormal	129	96
#H	9	48	Lognormal	104	104
#I	9	45	Lognormal	72	83
#J	9	37	Lognormal	72	76

[4] Subsequent to the 2002 school sampling effort, Ecology and Health Department staff have collected soil samples from other schools in Eastern and Central Washington. Staff from Ecology, the Department of Health and local health agencies are compiling and evaluating the sampling results. In general, sampling results indicate that soil contamination levels at most of the schools have soil contamination levels that are lower than the levels found at the Wenatchee schools with the more contaminated soils.

Table 6: Arsenic Concentrations from Three Child Play Areas at One Wenatchee Area Schools			
Sample Location	Play Area A	Play Area B	Play Area C
1	25	65	138
2	27	142	156
3	96	44	318
4	33	176	111
5	63	47	185
6		182	51
7		199	

Methods and Assumptions

Methods to Characterize Health Risks

Potential exposures and health risks were estimated using modified versions of the equations for establishing soil cleanup standards under the Model Toxics Control Act.

Non-Carcinogenic Health Risks: Ecology used the hazard quotient as a measure of non-carcinogenic health risks. The hazard quotient is a function of two factors: (1) the reference dose; and (2) estimates of the average daily exposure over a six year exposure period (chronic exposure) or several days or weeks (less-than-lifetime exposure).

$$HazardQuotient(HQ) = \frac{AverageDailyDose(ADD)}{referenceDose}$$

Key assumptions underlying the methods used to characterize non-carcinogenic health risks include:

- The ratio of the average daily dose and the reference dose provides a reasonable measure of non-cancer health risks;
- The reference dose for a particular chemical (in this case – arsenic) is a reasonable measure of toxicity; and
- For a given level of response, concentration (or dose) multiplied by time of exposure is a constant (e.g. exposure at 1 ug/kg/day for 5 days/week for one year is equivalent to 0.7 ug/kg/day for 7 days/week for one year.)

- **Carcinogenic Risks**: Ecology used estimates of incremental lifetime cancer risks as a measure of carcinogenic risk. Estimates of incremental lifetime cancer risk are a function of two factors: (1) Cancer slope factor which describes the quantitative relationship between incremental cancer risk and exposure; and (2) estimates of the average daily exposure over a person's lifetime.

$$IncrementalLifetimeCancerRisk = (CancerSlopeFactor) * (LifetimeAverageDailyDose$$

Key assumptions underlying the methods used to characterize carcinogenic risks include:

- The model is a reasonable approach for evaluating the incremental cancer risk associated with arsenic-contaminated soils;
- For a given level of response, concentration (or dose) multiplied by time of exposure is a constant; and
- The cancer slope factor is a reasonable measure for characterizing the carcinogenic potency of arsenic; and
- Arsenic exposure early in life has the same effect as a comparable level of exposure later in life.

Toxicological Parameters

A wide range of health effects have been associated with exposure to arsenic. These include skin problems (e.g. hyper-pigmentation, hyperkeratoses), gastrointestinal problems (e.g. nausea, diarrhea, stomach pain), nerve damage, diabetes, cardiovascular effects (e.g. hypertension) and several forms of cancer (e.g. skin, bladder, lung). In general, cancer is considered the most sensitive health endpoint. Ecology used four measures of arsenic toxicity and carcinogenicity in the initial evaluations:

- Slope Factor (oral and dermal exposure): Two slope factors (1.5 and 3.7 $(mg/kg/day)^{-1}$) were initially used to characterize the relationship between exposure to inorganic arsenic and the increased likelihood of developing cancer. The first value (1.5 $(mg/kg/day)^{-1}$) was obtained from the Integrated Risk Information System (IRIS) database and is based on increased rates of skin cancer observed in populations exposed to elevated levels of arsenic in drinking water. The second value (3.7 $(mg/kg/day)^{-1}$) is based on the National Research Council's and Environmental Protection Agency's evaluation of studies where increased rates of bladder and lung cancer were observed in populations exposed to elevated levels of inorganic arsenic in drinking water.
- Reference Dose (chronic oral and dermal exposure): A chronic oral reference dose of 0.0003 mg/kg/day was used to evaluate the potential for non-cancer health risks associated with chronic exposure to arsenic-contaminated soils. This value was obtained from the IRIS database and is based on studies where increased rates of skin lesions were observed in populations exposed to elevated levels of inorganic arsenic in drinking water.
- Reference Dose (less-than-lifetime oral and dermal exposure): A less-than-lifetime oral reference dose of 0.005 mg/kg/day was used to evaluate the health risks associated with acute and sub-chronic exposure to arsenic-contaminated soils. This value is based on evaluations of health studies and case reports prepared by the Washington Department of Health (DOH) and the Agency of Toxics Substances and Disease Registry (ATSDR).
- Slope Factor (inhalation exposure): A slope factor of 15.1 $(mg/kg/day)^{-1}$ was used to evaluate the health risks associated with inhalation exposure to arsenic-contaminated soils. This value was obtained from the IRIS database and is based on studies where increased rates of lung cancer were observed in smelter workers.

Population at Risk

When developing the working definition, Ecology focused on risks to young children. Young children are the population group with the highest potential for exposure to arsenic-contaminated soils. Although adults may also be exposed to arsenic-contaminated soils, Ecology assumed that a working definition based on child exposure will also protect adults.

Exposure Pathways

Children may be exposed to contaminated soils through a variety of pathways. When developing the working definition, Ecology considered exposures resulting from (1) incidental ingestion of soil and dust, (2) dermal contact with contaminated soils, (3) inhalation of windblown dust and (4) ingestion of homegrown vegetables and fruits grown in arsenic-contaminated soils.

Methods and Parameters Used to Characterize Exposure

Child exposures were evaluated using the exposure models included in the Model Toxics Control Act (MTCA) Cleanup Regulation (e.g. parameters included in the equation for establishing soil cleanup standards based on incidental soil ingestion and dermal contact) and relevant EPA guidance materials. Ecology used three measures to characterize potential exposure:

- Lifetime Average Daily Dose (LADD);
- Average Daily Dose (ADD) for chronic exposure; and
- Average Daily Dose (ADD_{ST}) for short-term or acute exposure (soil ingestion pathway).

The method and parameters used to estimate exposure to contaminated soils are summarized in Figures 1 and 2.

Ecology also evaluated the variability in exposure estimates by performing a simple Monte Carlo analysis. This involved replacing the point estimates for several input parameters with probability distributions for those values. The simulation was run using the Crystal Ball software program using 10,000 iterations per simulation. Several simulations were run using each set of parameters in order to evaluate the stability of the results. The following distributions were used in the analysis.

- The **soil ingestion rate** was characterized using a lognormal distribution with a mean of 60.6, standard dev. of 80.5, and lower & upper bounds of 0 and 500, respectively.
- The **GI absorption fraction** was characterized using a triangular distribution (0.6, 0.8, 1.0).
- The **skin adherence factor** was characterized using a lognormal distribution with a geometric mean of 0.11 and geometric standard deviation of 2.0 and an upper bound of 10.
- The **dermal absorp. factor** was characterized using a triangular distribution (0.01,0.03,0.06).
- **Fraction ingested as soil** was characterized as triangular distribution (0.1, 0.45, 0.80).
- **Soil/dust concentration ratio** was characterized using a lognormal distribution with a mean of 0.45, standard deviation of 0.17 and lower and upper bounds of 0.2 and 0.92.
- **Child body weight** was characterized as a lognormal distribution with an arithmetic mean of 15.5, standard deviation of 2.05, a lower bound of 4 and an upper bound of 50.

The initial analyses indicated that 3 variables (soil/dust concentration ratio, fraction ingested as soil and child body weight) contributed less than 1 percent to the overall variability. Subsequent simulations were conducted using point estimates for these values.

Key Assumptions

Ecology has evaluated the health risks posed by arsenic-contaminated soils to support decisions on how to implement recommendations the Department received from the Area-wide Soil Contamination Task Force. In performing that evaluation, Ecology made several underlying assumptions:

- The methods used to establish soil cleanup levels under MTCA provide a technically sound approach for evaluating the relationship between soil arsenic concentrations and health risks.
- Surface soils with arsenic concentrations below 100-200 mg/kg are unlikely to pose a significant threat to ground water supplies.

- Ecological impacts will be considered when deciding what should be done to address elevated levels of arsenic at individual properties.
- Other contaminants commonly associated with smelter emissions are not present at levels that are high enough to trigger the need for actions that are different than those needed to address arsenic and lead. This is consistent with the results of the baseline risk assessment for the Ruston/North Tacoma Superfund site (Glass and SAIC, 1992)[5] and the Everett Smelter Project (Ecology, 1999).
- The working definition will be periodically reviewed based on new information.

Figure 1

Exposure Model for Incidental Ingestion of Soil and Dust

$$LADD / ADD = \frac{C_s \cdot SIR \cdot AB1 \cdot EF \cdot ED}{ABW \cdot AT \cdot UCF_1}$$

Where:

LADD = Lifetime average daily dose (LADD) (mg/[kg-d])
ADD = Average daily dose (mg/[kg·d])
ABW = Child body weight (kg)
AB1 = Gastrointestinal absorption factor (unitless)
AT = Averaging time (yr)
C_s = Contaminant concentration in soil (mg/kg)
EF = Exposure frequency (unitless)
ED = Exposure duration (yr)
SIR = Incidental soil ingestion rate (mg/d)
UCF_1 = Unit conversion factor (mg/kg)

Parameter	Units	LADD	ADD	$ADD_{(ST)}$
ABW	kg	16	16	16
AB1	unitless	1.0	1.0	1.0
AT	yr	75	6	NA
C_s	mg/kg	Variable	Variable	Variable
EF	unitless	1.0	1.0	1.0
ED	yr	6	6	NA
SIR	mg/day	200	200	5000
UCF_1	mg/kg	1,000,000	1,000,000	1,000,000

[5] Glass and SAIC (1992) evaluated a range of other metals associated with smelter operations using a conservative (health protective) screening level analysis. The authors concluded that the levels found in the neighborhoods near the smelter did not individually result in significant health risks. However, the authors also noted that low levels of other contaminants may interact with arsenic and lead in ways that modify (increase or decrease) the toxicity of these two substances.

Figure 2

Exposure Model for Dermal Contact

$$LADD / ADD = \frac{C_s \cdot SA \cdot AF \cdot ABS_d \cdot EF \cdot ED}{ABW \cdot AT \cdot UCF_1}$$

Where:

LADD = Lifetime average daily dose (mg/[kg-d])
ADD = Average daily dose (mg/[kg·d])
ABS_d = Dermal absorption factor (unitless)
ABW = Child body weight (kg)
AF = Soil- to-skin adherence factor (mg/cm^2·d)
AT = Averaging time (yr)
C_s = Contaminant concentration in soil (mg/kg)
EF = Exposure frequency (unitless)
ED = Exposure duration (yr)
SA = Exposed surface area (cm^2)
UCF_1 = Unit conversion factor (mg/kg)

Parameter	Units	LADD	ADD
ABS_d	unitless	0.03	0.03
ABW	kg	16	16
AF	mg/cm^2-day	0.2	0.2
AT	yr	75	6
C_s	mg/kg	Variable	Variable
EF	unitless	1.0	1.0
ED	yr	6	6
SA	cm^2	2,200	2,200
UCF_1	mg/kg	1,000,000	1,000,000

Evaluation Results

- **Estimates of Non-Carcinogenic Health Risks**: Tables 7 and 8 summarize the hazard quotient values calculated using several measures of exposure and two reference doses. In 2001, Ecology used the highlighted hazard quotient values (3 for school and child care facilities and 4.3 for residential areas) to characterize the non-cancer health risks associated with arsenic soil concentrations of 100 mg/kg. The results from the Monte Carlo analysis indicate that the exposure estimates fall at the upper end of the simulated distribution corresponding to a reasonable maximum exposure. Use of the chronic reference dose derived from analyses performed by the California Office of Environmental Health Hazard Assessment (OEHHA) increases the calculated HQ values by a factor of 2.5 for comparable levels of exposure.

Table 7: Schools and Child Care Exposure Scenario			
Range of Estimated Hazard Quotient Values Associated with Exposure to Arsenic at 100 mg/kg			
Exposure Estimate (mg/kg/day)		Chronic RfD (mg/kg/day)	
		3.0E-04	1.2E-04[6]
MTCA Point Est.	9.1E-04	3.0E+00	7.6E+00
Monte Carlo (Mean)	2.2E-04	7.5E-01	1.9E+00
Monte Carlo (90th)	4.3E-04	1.4E+00	3.6E+00
Monte Carlo (95th)	6.2E-04	2.1E+00	5.1E+00

Table 8: Residential Exposure Scenario			
Range of Estimated Hazard Quotient Values Associated with Exposure to Arsenic at 100 mg/kg			
Exposure Estimate (mg/kg/day)		Chronic RfD (mg/kg/day)	
		3.0E-04	1.2E-04
MTCA Point Estimate	1.3E-03	4.3E+00	1.1E+01
Monte Carlo (Mean)	3.2E-04	1.1E+00	2.7E+00
Monte Carlo (90th)	6.2E-04	2.1E+00	5.2E+00
Monte Carlo (95th)	8.8E-04	2.9E+00	7.3E+00

Hazard quotient estimates for the park exposure scenario ranged from 0.5 to 4. These values were 40 percent of the hazard quotient values for the schools/child care exposure scenario due to the different exposure frequency assumptions (5 days/week for schools/child care facilities vs 2 days/week for the parks exposure scenario).

[6] In December 2004, the MTCA Science Advisory Board recommended that Ecology use a chronic reference dose of 0.00012 mg/kg/day to characterize the range of potential non-cancer health risks. Although not part of the original analyses, this reference dose value is included in Tables 7 and 8 in order to illustrate how the lower value impacts the calculated hazard quotient values (See Issue #2).

- **Estimates of Incremental Lifetime Cancer Risks**: Tables 9 and 10 summarize the incremental cancer risk estimates developed using several measures of exposure and cancer slope factors. In 2001, Ecology used the highlighted risk estimates (1.1×10^{-4} for school and child care facilities and 1.7×10^{-4} for residential areas) to characterize the cancer risks associated with arsenic soil concentrations of 100 mg/kg. The results from the Monte Carlo analysis indicate that the exposure estimates fall at the upper end of the simulated distribution corresponding to a reasonable maximum exposure. Use of more recent cancer slope factors developed by EPA and OEHHA result in estimated risks that are 2-6 times higher than the estimated risks based on the slope factor published in the IRIS database.

Table 9: School and Child Care Exposure Scenario

Estimated Incremental Cancer Risks at Arsenic Soil Concentration of 100 mg/kg

Exposure Estimate (mg/kg/day)		Cancer Slope Factor[7]			
		1.5	3.7	5.7	9.4
MTCA Point Estimate	7.5E-05	1.1E-04	2.8E-04	4.3E-04	7.1E-04
Monte Carlo - Mean	1.8E-05	2.7E-05	6.7E-05	1.0E-04	1.7E-04
Monte Carlo - 90th	3.5E-05	5.3E-05	1.3E-04	2.0E-04	3.3E-04
Monte Carlo - 95th	4.9E-05	7.4E-05	1.8E-04	2.8E-04	4.6E-04

Table 10: Residential Exposure Scenario

Estimated Incremental Cancer Risks at Arsenic Soil Concentration of 100 mg/kg

Exposure Estimate (mg/kg/day)		Cancer Slope Factor			
		1.5	3.7	5.7	9.4
MTCA Point Est.	1.1E-04	1.7E-04	4.1E-04	6.3E-04	1.0E-03
Monte Carlo - Mean	2.6E-05	3.9E-05	9.6E-05	1.5E-04	2.4E-04
Monte Carlo - 90th	5.0E-05	7.5E-05	1.9E-04	2.9E-04	4.7E-04
Monte Carlo - 95th	7.0E-05	1.1E-04	2.6E-04	4.0E-04	6.6E-04

Incremental cancer risks for the parks exposure scenario ranged from 1 x 10-5 to 2 x 10-4. These values were 40 percent of the incremental cancer risk estimates for the schools/child care exposure scenario due to the different exposure frequency assumptions (5 days/week for schools/child care facilities vs 2 days/week for the parks exposure scenario).

[7] In November 2004, the MTCA Science Advisory Board recommended that Ecology use slope factors based on bladder and lung cancer when evaluating potential cancer risks. Although not part of the original analyses, two additional cancer slope factors (5.7 and 9.4 mg/kg/day^{-1}) are included in Tables 9 and 10 to illustrate how the higher slope factor values impact the calculated cancer risk estimates. (See Issue #1)

Cancer Slope Factor

Question #1:

Does the SAB agree with Ecology's conclusion that there is clear and convincing scientific evidence to support the use of an oral slope factor for inorganic arsenic that is significantly different than the value published in the IRIS database? If yes, does the SAB agree with Ecology's conclusion that slope factors between 3.7 & 23 $(mg/kg/day)^{-1}$ represent a range of scientifically defensible values?

Ecology Rationale

Ecology concluded that there is clear and convincing scientific evidence supporting the development and use of an oral slope factor based on increased rates of bladder and lung cancer. Studies conducted in Taiwan, Chile, Argentina and Japan provide (1) sufficient evidence to conclude that ingestion of inorganic arsenic increases the risk of developing lung and bladder cancers and (2) dose-response data that is sufficient to calculate an oral slope factor. The range of slope factors calculated from these studies (3.7 – 23 $(mg/kg/day)^{-1}$) represents a range of scientifically plausible values for use in evaluating health risks associated with arsenic-contaminated soils. The rationale for these conclusions includes:

- The methods used to develop the range slope factors are based on theories, techniques/principles that have widespread acceptance within the toxicology and risk assessment community.
- The range of cancer slope factors developed by different agencies and scientific panels are all based on the results from peer-reviewed studies using widely accepted risk assessment methods.
- Ecology has reviewed the reports from scientific review committees, the current scientific literature and recent regulatory analyses in order to identify key issues and the range of viewpoints on those issues. Ecology's conclusions were heavily influenced by the viewpoints of the NRC panel.[8]
- The key assumptions underlying the cancer slope factor are valid and appear to err on behalf of protection of human health.
- The range of slope factors adequately address populations that are more highly exposed (e.g. young children) than the general population.
- Ecology has relied on studies/analyses that have been subjected to extensive public & peer review.

SAB Conclusions and/or Requests for Additional Information

In November 2004, the Board reviewed the materials prepared by Ecology and concluded:

- The Board agreed with Ecology's conclusion that there is clear and convincing scientific evidence to support the use of an oral slope factor for inorganic arsenic that is significantly different than the IRIS value.
- The Board agreed with Ecology's conclusion that slope factors between 3.7 and 23 $mg/kg/day^{-1}$ represent a range of scientifically defensible values.
- The Board recommended that Ecology consider refining the range of values based on further consideration of the methodologies used by other agencies, the forms of inorganic arsenic likely to

[8] NRC (2001) concluded that "...internal cancers are more appropriate as an endpoint for risk assessment than non-melanomic skin cancer because internal cancers are more life-threatening..." (p. 68); and (2) study results from Taiwan, Chile and Argentina indicate that excess deaths attributable to skin cancer represent <1 to 10 percent of the total excess cancer deaths due to lung, bladder, kidney and skin cancer observed in those studies.

be present in soils (relative to the forms of arsenic that study populations were exposed to) and other factors.

Ecology Response to Issues Identified by the Board

The EPA Science Advisory Board is currently reviewing several issues associated with arsenic carcinogenicity. At a September 2005 meeting, EPA staff discussed a draft IRIS value based on lung and bladder cancer incidence (5.7 $mg/kg/day^{-1}$). The subcommittee was scheduled to continue discussing this issue on December 5th. However, EPA has postponed that meeting until early 2006.

Background Information

EPA has published an oral slope factor (1.5 $mg/kg/day^{-1}$) in the Integrated Risk Information System (IRIS) database. The value in the IRIS database is based on a study where increased rates of skin cancer were observed among residents in villages in southwestern Taiwan where drinking water wells had elevated levels of arsenic.

Several agencies and scientific panels have developed cancer slope factors or unit risk values based on other cancer endpoints (e.g. lung, bladder & liver) since EPA published the IRIS value. Ecology summarized values used by various agencies in the discussion materials distributed in November 2004 (See Table 11). Subsequent to the November 2004 Board meeting, EPA staff developed a draft cancer slope factor based on lung and bladder cancer which is currently being reviewed by a subcommittee of the EPA Science Advisory Board.

Table 11: Summary of Range of Carcinogenic Slope Factors ($(mg/kg/day)^{-1}$)

Source	Value	Cancer Type	Studies	Extrapolation Method
Integrated Risk Info. System (IRIS) (EPA, 1998)	1.5	Skin	Tseng et al. 1968; Tseng, 1977	Multistage model (Time- and dose-related formulation)
National Research Council (1999)	1.1	Bladder	Chen et al. 1985, 1988, 1992; Wu et al. 1989	Multiplicative Poisson model
EPA Office of Drinking Water (EPA, 2001a)	0.4 - 3.7	Bladder & Lung	Chen et al. 1985, 1988, 1992; Wu et al. 1989	Multiplicative Poisson (Morales et al. 2000)
National Research Council (2001)	2.1 – 14.1	Bladder & Lung	Chen et al. 1985, 1992; Wu et al. 1989	Additive Poisson model
Consumer Product Safety Commission (CPSC, 2003)	0.4 – 23	Bladder & Lung	Chen et al. 1985, 1988, 1992; Wu et al. 1989	Combination of EPA (2001a) & NRC (2001)
EPA Office of Pesticide Programs (EPA, 2003a)	3.7	Bladder & Lung	Chen et al. 1985, 1988, 1992; Wu et al. 1989	Based on EPA (2001a)
CA Office of Environmental Health Hazard Assessment (2004)	9	Bladder & Lung	Chen et al. 1985, 1988; Hopenhyn-Rich et al. 1996, 1998; Ferriccio et al. 2000; Smith et al. 1998; Tsuda et al. 1995	
Environmental Protection Agency (2005)	5.7	Bladder & lung		

Ecology believes that all of the slope factors summarized in Table 11 have a plausible scientific basis. However, there are several sources of uncertainty and variability that complicate the interpretation and use of these values. While some of the variability in values in Table 11 reflects the fact that the values were developed at different times (with newer information being available for more recent values), much of the variability is due to the different approaches used to address these sources of uncertainty and variability. Specifically, the range of values reflects differences in the following:

- **Choice of Cancer Endpoint Used to Develop Slope Factors**: Chronic exposure to inorganic arsenic in drinking water has been found to be associated with increased risk of developing lung, bladder, skin and kidney cancer. Some of the variation in published slope factors is due to the fact that the available values are based on different cancer endpoints or combinations of cancer endpoints: (1) the slope factor published in the IRIS database is based on skin cancer prevalence data; (2) the NRC (1999) value is based on bladder cancer mortality; and (3) the EPA (2001), NRC (2001) and OEHHA (2004) values are based on bladder and lung cancer mortality data. Given current information, approaches based on a combination of lung and bladder cancer are considered superior to approaches based on a single cancer endpoint. However, use of this approach reflects an underlying assumption that lung and bladder cancer are the most important contributors to overall cancer risk. The OEHHA (2004) evaluated this assumption by incorporating the added risk of dying from skin and kidney cancer by using the ratio of the total excess cancer deaths relative to excess lung cancer deaths from all studies. Based on that analysis, OEHHA concluded that cancer potency estimates based on all four cancer endpoints was approximately 20 percent higher than potency estimates based solely on lung and bladder cancer.

- **Choice of Mathematical Model Used to Estimate Cancer Risks**: The shape of the dose-response curve for arsenic-induced cancer is one of the largest sources of uncertainty in arsenic risk assessment. There is currently no clear biological basis for selecting a model to extrapolate results from high to low arsenic exposures. Most recent scientific reviews (NRC 1999; EPA, 2000d; and NRC, 2001) have each concluded that the general Poisson approach is an appropriate method for evaluating cancer risks posed by oral exposure to inorganic arsenic. However, choices on the shape of the dose-response relationship, relative risk model (additive vs multiplicative) and comparison population (internal vs external) all impact cancer slope factor estimates

- **Choice of Methods and Assumptions Used to Estimate Exposure in Study Populations**: The primary studies used to develop cancer slope factors used broad exposure classifications based on the levels of arsenic in village drinking water wells. When calculating a cancer slope factor, the risk assessor must make assumptions regarding (1) the amount of water consumed in the study population and U.S. population, (2) the amount of arsenic exposure resulting from dietary exposure; and (3) the average body weights in the both the study and U.S. population. The various analyses have been performed using different assumptions about drinking water intake, dietary exposure and body weights. In general, assumptions that lead to higher arsenic exposure estimates (mg/kg/day) in the study population result in lower cancer slope factor estimates.

Oral Reference Dose (Chronic)

Question #2

Does the SAB agree with Ecology's conclusion that the chronic oral reference dose (0.0003 mg/kg/day) published in the IRIS database remains an appropriate value for use in evaluating chronic human exposure to soils?

Ecology Rationale

Ecology concluded that the chronic oral reference dose published in the IRIS database remains an appropriate value for use in evaluating chronic human exposure to arsenic-contaminated soils. The primary rationale for this conclusion includes three main considerations: (1) the IRIS value was developed through a process that considered available studies, uncertainties and potential confounding factors; (2) the primary study used to estimate a NOAEL involved a large study population that included sensitive individuals; and (3) EPA applied an uncertainty factor of 3 to account for lack of data on reproductive toxicity as a critical effect and some uncertainty on whether the NOAEL accounts for all sensitive individuals. Ecology is aware that several studies published subsequent to the completion of the EPA value provide sufficient dose-response information to calculate reference doses for other types of non-cancer health effects (other than skin lesions). The range of calculated values includes values that are an order of magnitude higher or lower than the IRIS value. However, the vast majority of calculated values fall within a factor of 3 (higher or lower) than the IRIS value which is similar to the range of uncertainty reflected in EPA's guidance on the use of the current IRIS value[9].

- The methods used to develop the range of chronic reference doses for arsenic are based on theories, techniques and principles that have widespread acceptance within the toxicology and risk assessment community.
- The range of chronic oral reference doses developed by different agencies, scientific panels and individuals are all based on the results from peer-reviewed studies that have been evaluated using widely accepted risk assessment methods.
- Ecology has reviewed the reports from scientific review committees, the current scientific literature and recent regulatory analyses in order to identify key issues and the range of viewpoints on those issues.
- The key assumptions underlying the chronic oral reference doses are valid and appear to err on behalf of protection of human health.
- The range of chronic oral reference doses appears to adequately address populations that are more highly exposed (e.g. young children) than the general population.
- Ecology has relied on studies and committee analyses that have been subjected to extensive public and peer review.

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[9] EPA (1998) stated "...[t]here was not a clear consensus among Agency scientists on the oral RfD. Applying the Agency's RfD methodology, strong scientific arguments can be made for various values within a factor of 2 or 3 of the currently recommended RfD value, i.e. 0.1 to 0.8 ug/kg/day. It should be noted, however, that the RfD methodology, by definition, yields a number with inherent uncertainty spanning perhaps an order of magnitude. New data that possibly impact on the recommended RfD for arsenic will be evaluated by the Work Group as it becomes available. Risk managers should recognize the considerable flexibility afforded them in formulating regulatory decisions when uncertainty and lack of clear consensus are taken into account."

SAB Conclusions and/or Requests for Additional Information

In December 2004, the Board reviewed the discussion materials prepared by Ecology on this issue and concluded:

- The Board disagreed with Ecology's conclusion that the chronic oral reference dose published in the IRIS data remains an appropriate value for use in evaluating chronic human exposure to arsenic-contaminated soils.
- The Board concluded there is now enough scientific information to consider other non-cancer health endpoints in addition to skin lesions.
- The Board concluded that the reference dose value developed by the California Office of Environmental Health Hazard Assessment appears to be reasonable, but recommended that Ecology review the basis for this value in terms of whether it is appropriate to use to evaluate health risks in Washington.

Background Information

EPA has published a chronic oral reference dose for inorganic arsenic (0.0003 mg/kg/day) in the Integrated Risk Information System (IRIS) database that is based on studies by Tseng et al. (1968) and Tseng (1977) which reported an increased incidence of skin lesions (e.g., hyperpigmentation and keratosis) and possible vascular complications among residents of Taiwan villages found to have elevated levels of arsenic in drinking water.

Most agencies continue to use the EPA chronic reference dose to evaluate non-cancer health risks. However, two agencies have developed different values since EPA published the IRIS value. Ecology summarized values used by various agencies in the discussion materials distributed in November 2004 (See Table 12).

Table 12: Chronic Oral Reference Doses (mg/kg/day)

Source	RfD	Primary Studies	Critical Effects	NOAEL/ LOAEL	Uncertainty Factors
Environmental Protection Agency (EPA, 1998)	3 E-04	Tseng, 1977; Tseng et al. 1968	Skin lesions	0.0008 (NOAEL)	3X (human variability)
Agency for Toxic Substances & Disease Registry (ATSDR, 2000)	3 E-04	Tseng, 1977; Tseng et al. 1968.	Skin lesions	0.0008 (NOAEL)	3X (human variability)
Consumer Product Safety Commission (CPSC, 2003)	8 E-05	Tseng, 1977; Tseng et al. 1968	Skin lesions	0.0008 (NOAEL)	10X (human variability)
California Office of Environmental Health Hazard Assessment (2004)	1.2 E-04	Chiou et al. 1997	Cerebrovascular disease	3 (mg/L)yr (LED01 = LOAEL)	10X (human variability)

The chronic reference dose values summarized above are based on current scientific information. However, there are a number of issues associated with calculating such values for arsenic that are not fully resolved from a scientific standpoint. These issues include:

- <u>Identification of Critical Endpoints</u>: When considering the range of non-cancer health effects associated with inorganic arsenic exposure, skin lesions are generally considered to be the most sensitive endpoint. The EPA reference dose is based on skin lesions (hyperpigmentation, keratoses). However, there is some uncertainty on whether skin lesions represent the critical effect. For example, when establishing the RfD value, EPA noted there was limited data an reproductive effects and applied a 3X modifying factor to account for this data gap. The National Research Council (1999, 2001) summarized a number of recent scientific studies where an association between elevated levels of inorganic arsenic in drinking water and increased rates of hypertension and diabetes had been reported (Rahman et al. 1998, 1999; Chen, et al. 1995, 1996). More recently, the California OEHHA (2004) has completed an extensive review of the scientific literature to support California's efforts to establish health protection concentrations for arsenic in drinking water. As noted above, the OEHHA prepared dose response assessments based on several different health endpoints using EPA's benchmark dose software and used those values to identify a range of health protection concentrations based on non-cancer effects. Table 7 summarizes the range of health protection concentrations calculated by OEHHA and the reference dose values that correspond to those concentrations. OEHHA (2004) based the non-cancer health protection goal (0.9 ug/L) on their analysis of the results from Chiou et al. (1997). The reference dose (1.2 E-04 mg/kg/day) corresponding to this health protection concentration is 2.5 times lower than the EPA value.

- Identification of a Point of Departure (e.g. NOAEL, LOAEL, ED, LED): Results from animal bioassays or human epidemiology studies/case reports are used to identify a point of departure. Traditionally, the point of departure is defined by either the "no observed adverse effect level" (NOAEL) or "lowest observable adverse effect" (LOAEL). However, EPA has developed the Benchmark Dose software package that can be used to calculate Benchmark Doses (BMD) or Effective Doses (ED) values that can be used to define the point of departure.

- Model Selection and Parameter Choices: Selection of the point of departure is influenced by choices made by the risk assessor with respect to (1) methods for identifying point of departure (BMD approach vs single dose); (2) dose metric used in the analysis; and (3) effective dose used to estimate point of departure (e.g. LED_{01}, LED_{05}, LED_{10}). Table 13 illustrates how the choice of extrapolation model influences the identification of a point of departure calculated from Chiou et al. (1997).

Table 13: Comparison of Benchmark Dose Values Based on Dose Response Information for Cerebrovascular Disease (Chiou et al. (1997)

Method	Dose Metric	BMD_{01}/ED_{01}	$BMDL_{01}/LED_{01}$	Chi^2
Quantal Linear	ug/L	359	189	4.24
Quantal Quadratic	ug/L	422	292	4.98

- Exposure Estimates: The primary studies available for calculating reference doses are human studies which generally use broad exposure classifications. When calculating a reference dose, the risk assessor must make assumptions regarding (1) the amount of water consumed in the study population and U.S. population, (2) the amount of arsenic exposure resulting from dietary exposure; and (3) the average body weights in the both the study and U.S. population. The assumptions used to estimate exposure can have a large impact on the calculation results. In general, assumptions that lead to higher arsenic exposure estimates (mg/kg/day) in the study population result in higher reference dose estimates. For example, the studies that formed the basis for the chronic reference dose (Tseng 1977; Tseng, et al. 1968) contain limited information on arsenic exposure other than the average drinking water concentrations in each village. In calculating the NOAEL value, EPA made several assumptions on water intake and dietary intake of arsenic in order to express the NOAEL value in units of mg/kg/day[10]. NRC (2001) reviewed these assumptions (in the context of cancer risks) and recommended the use of different estimates for water intake and dietary contributions of arsenic. Use of the NRC values would result in a calculated NOAEL that is slightly higher than the EPA value (0.001 mg/kg/day vs 0.0008 mg/kg/day). However, the difference between the two values is well within the range of plausible values identified by EPA in the IRIS summary.

- Uncertainty and Modifying Factors: EPA applies several uncertainty factors to the point of departure to derive the reference dose. These uncertainty factors are designed to take into account (1) variations in response among different species (UF_A) (2) variations in individual sensitivity (UF_H); (3) extrapolation from results involving less-than-chronic exposure (UF_S); (4) extrapolation from a LOAEL to a NOAEL (UF_L); (5) data gaps (UF_D). An uncertainty factor of 1, 3 or 10 is assigned, as appropriate, to each of these areas with cumulative uncertainty factors ranging from 1 to 1000 or more. When preparing the reference dose for arsenic, EPA used an uncertainty factor of 3 to account for the limited data on reproductive effects and uncertainty on whether the Taiwan studies fully accounted for variations in susceptibility within human population groups. OEHHA (2004) applied an uncertainty factor of 10 to the LED01 to account for variations in individual sensitivity.

[10] EPA used the exposure assumptions similar to those used in calculating the oral slope factor: (1) the average arsenic levels in drinking water were 0.009 mg/L which was the arithmetic mean of a range of values from 0.001 to 0.017; (2) the average person consumed 4.5 L of water/day and weighed 55 lbs.; (3) consumption of sweet potatoes and rice were assumed to contribute an additional 0.002 mg/day of arsenic.

Oral Reference Dose (Less-Than-Lifetime)

Question #3: Does the SAB agree with Ecology's conclusion that there is clear & convincing scientific evidence to support the use of an acute reference dose for arsenic that is different than the chronic reference dose published in the IRIS database? If yes, does the SAB agree that a value of 0.005 mg/kg/day is within the range of scientifically defensible values?

Ecology Rationale

Ecology concluded that it was appropriate to use an oral reference dose of 0.005 mg/kg/day to characterize the health risks associated with acute and sub-chronic exposure to arsenic-contaminated soils. This value was developed by the Washington Department of Health (White, 1999) to support cleanup decisions at the Everett Smelter site and is consistent with the range of values being used by other state and federal environmental agencies. It was developed using widely accepted scientific methods.

- The methods used to develop the range of reference doses for less-than-lifetime exposure are based on theories, techniques and principles that have widespread acceptance within the toxicology and risk assessment community.
- The range of reference doses developed by different agencies, scientific panels and individuals are all based on the results from peer-reviewed studies that have been evaluated using widely accepted risk assessment methods.
- Ecology has reviewed the reports from scientific review committees, the current scientific literature and recent regulatory analyses in order to identify key issues and the range of viewpoints on those issues.
- The key assumptions underlying the chronic oral reference doses are valid and appear to err on behalf of protection of human health.
- The range of chronic oral reference doses adequately address populations that are more highly exposed (e.g. young children) than the general population.
- Ecology has relied on studies and committee analyses that have been subjected to extensive public and peer review.

SAB Conclusions and/or Requests for Additional Information

The Board reviewed the Ecology discussion materials at the December 2004 meeting. The Board did not reach a conclusion on the question posed by Ecology and requested that the Department provide the Board with the following additional information.

- Skin Keratosis: One Board member asked whether any of the available studies had looked at skin keratosis in children. Ecology responded that the less-than-lifetime RfD value developed by EPA Region VIII for the Vasquez Boulevard/I-70 Site is based on increased incidence of skin keratosis in children. However, EPA's Office of Pesticides Programs concluded that the children in the study population were probably exposed to arsenic for periods longer than 6-12 months.
- *In Utero* Exposures: The Board recommended that Ecology review a study by Waalkes et al. (2001) and consider whether it is appropriate to base a reference dose on health effects (such as cancer after birth) associated with *in utero* exposures. It was pointed out that the Waalkes et al. study is more recent than the studies on which the various federal values were based.

- Safety Factors: The Board requested that Ecology provide additional information on the Office of Pesticides Program's rationale for the use of a safety factor that is three-fold higher than the safety factors used by DOH and ATSDR.
- Other Available Toxicity Measures for Evaluating Acute and Subchronic Exposures: The Board recommended that Ecology determine if other agencies have developed toxicity measures for evaluating subchronic exposures (e.g. did the California Environmental Protection Agency consider health effects resulting from subchronic exposure when developing drinking water guidelines).

Background Information

The estimated LD50 from arsenic ingestion is approximately 1-4 mg/kg in humans (ATSDR, 2000). Oral exposure to high non-lethal doses of arsenic causes irritation of the GI tract which leads to nausea and vomiting. Other signs may include neuritis and vascular effects. The initial symptoms associated with sub-chronic exposure to arsenic include vague weakness and nausea. As exposure continues, effects may include diarrhea, vomiting, anemia, injury to blood vessels, damage to kidney and liver and impaired nerve function that leads to a "pins and needles" sensation in the hands and feet.

Several "less-than-lifetime" reference doses or equivalent toxicity measures have been developed to evaluate the health risks posed by exposure to elevated levels of arsenic. Those values are summarized in Table 14 and briefly discussed below.

Table 14: Less-Than-Lifetime Oral Reference Doses (mg/kg/day)

Source	RfD	Use	Primary Studies	Critical Effects	NOAEL/ LOAEL	Uncertainty Factors
Washington Department of Health (DOH, 1999)	0.005 (0.0036 – 0.0071)	Acute & Sub-chronic	Mizuta et al. (1956); Franzblau & Lilis (1979)	GI symptoms, facial edema, neuropathy, skin lesions	0.036 – 0.071 (LOAEL)	10X (LOAEL to NOAEL)
Agency for Toxics Substances & Disease Registry (ATSDR, 2000)	0.005	Acute	Mizuta et al. (1956)	GI symptoms, facial edema, neuropathy, skin lesions	0.05 (LOAEL)	10X (LOAEL to NOAEL)
Environmental Protection Agency (EPA, 2002)	0.015	Acute & Sub-chronic	Mazumder et al. (1998)	Skin keratosis	0.015	1
EPA Office of Pesticide Programs (OPP) (EPA, 2003)	0.0017	Acute & Sub-chronic	Mizuta et al. (1956) Franzblau & Lilis (1979)	GI symptoms, facial edema, neuropathy, skin lesions	0.05 (LOAEL)	3X (intraspecies) 10X (LOAEL to NOAEL)

The "less-than-lifetime" reference doses summarized above are based on current scientific information. However, there are a number of issues associated with calculating such values for arsenic that are not fully resolved from a scientific standpoint. These issues are similar to those discussed in earlier sections and include: (1) Uncertainty in arsenic exposure levels in studies; (2) Uncertainty factors used to account for intra-individual variations in sensitivity; (3) Uncertainty factors used to extrapolate from LOAELs to NOAELs; and (4) Identification of critical effects. The different conclusions reached by the four evaluations (EPA, 2003;

White, 1999; ATSDR, 2000; EPA, 2002) reflect different approaches for addressing these sources of uncertainty.

- EPA (2003) developed a reference dose of 0.0017 mg/kg/day using an uncertainty factor of 30 to extrapolate from the LOAEL to a NOAEL. This was based on recommendations from the FIFRA Scientific Advisory Panel charged with reviewing EPA's approach for evaluating the health risks posed by the use of chromated copper arsenate (CCA) treated wood. The arguments in support of this approach are summarized in the minutes from the FIFRA Scientific Advisory Panel meeting held on October 23-25, 2001. Those arguments include:
    - A LOAEL of 0.05 mg/kg/day is an appropriate LOAEL for evaluating the toxic effects associated with short (1-30 days) and intermediate- (31-180 day) arsenic exposure. The FIFRA panel concluded that, while confidence in dose estimates from Mizuta et al. (1956) and Franzblau and Lilis (1979) is low, the confidence in 0.05 as an appropriate LOAEL is "quite high" given that other clinical studies have reported symptoms associated with the ingestion of inorganic arsenic.
    - A 10-fold uncertainty factor is appropriate for extrapolating from the LOAEL to a NOAEL because of (1) the severity of symptoms noted in some patients near or moderately above a LOAEL of 0.05 mg/kg/day (e.g. peripheral neuropathy, gastrointestinal bleeding, liver damage, low blood counts, CNS dysfunction and abnormal electrocardiograms); (2) humans appear to more sensitive to arsenic toxic effects than animals; and (3) there is little information on the dose-response relationships for arsenic.
    - The majority of the Panel recommended the use of an additional intraspecies uncertainty factor of 3 to provide for the protection of children. This was based on three main factors: (1) there are groups of children that are at special risk of arsenic toxicity due to nutritional deficiencies and/or concurrent exposure to other components of chromated copper arsenate (CCA); (2) there is a high level of uncertainty on the toxicokinetics of arsenic and it's metabolites in children; and (3) there is inadequate information on neurological effects of arsenic exposure at or near the LOAEL value.
- White (1999) and ATSDR (2000) both developed a reference dose (or equivalent measure) of 0.005 mg/kg/day using an uncertainty factor of 10 to extrapolate from the LOAEL to a NOAEL. The arguments in support of this approach include:
    - A LOAEL of 0.05 mg/kg/day is an appropriate LOAEL for evaluating the toxic effects associated with short-term arsenic exposure. The LOAEL is based on the results from several studies and clinical reports.
    - A 10-fold uncertainty factor is appropriate for extrapolating from the LOAEL to a NOAEL[11] because of (1) the severity of symptoms noted in some patients near or moderately above a LOAEL of 0.05 mg/kg/day (e.g. peripheral neuropathy, gastrointestinal bleeding, liver damage, low blood counts, CNS dysfunction and abnormal electrocardiograms); (2) humans appear to more sensitive to arsenic toxic effects than animals; and (3) there is little information on the dose-response relationships for arsenic.
    - Neither White (1999) nor ATSDR (2000a) included an additional uncertainty factor (similar to EPA 2003a). Tsuji et al. (2004) have argued against the use of uncertainty factors larger than 10 because (1) a reference dose of 0.005 mg/kg/day is less than an order of magnitude above

[11] Alternately, the 10 fold uncertainty factor could be viewed as including two parts: (1) a 3-fold UF for extrapolating from the LOAEL to the NOAEL and (2) a 3-fold UF to account for uncertainties in the database.

the chronic NOAEL and (2) the weight of evidence indicates that arsenic toxicity at lower exposure levels is a function of cumulative dose.

- EPA (2002) developed a reference dose of 0.015 mg/kg/day using an uncertainty factor of 3 to extrapolate from the LOAEL to a NOAEL. Tsuji et al. (2004) have reviewed the available information on arsenic health effects and summarized the arguments in support of this approach:
  - The NOAEL appears to be close to the LOAEL, within an order of magnitude or less;
  - Prevalence of effects is based on study populations that are generally 0-9 years old who have had more cumulative exposure (i.e. higher prevalence of effects) and possibly lower calculated dose-per-body weight than a time-weighted average dose from ages 0-6 years.
  - Exposed populations included malnourished children and other sensitive individuals (Chen et al., 2001a; Mazumder et al., 1998; Zaldivar and Guiller, 1977) which may increase susceptibility to arsenic health effects.
  - Populations evaluated for subchronic effects often had in utero exposure via drinking water. In a risk assessment application in soil, in utero exposure would be low because of the lower soil ingestion rates of adults/pregnant women compared to children.
  - Doses for water exposure in some studies (e.g. Mazumder et al., 1998) do not include additional exposure from inorganic arsenic in foods or dietary use of water (see Schoof et al., 1998; U.S. EPA, 2000). Thus actual exposure is greater in these cases.
  - Many of the studies include broad categories of exposure in which exposure misclassification (e.g. use of an average or median dose for a group with a range of exposure) has likely led to underestimation of exposure in study subjects exhibiting effects (Brown et al., 1997), and thereby potential downward bias in the LOAEL.

Exposure from Incidental Ingestion of Soil and House Dust

Question #4: Is the assumption that incidental ingestion of soil/dust represents an important exposure pathway for children and adults consistent with current scientific information?

Ecology's Rationale

Ecology has concluded that incidental ingestion of soil and dust represents an important exposure pathway for children and adults. This conclusion is based on the following factors:

- Results of Screening Level Analyses: Screening level analyses performed using the methods and assumptions in the MTCA Cleanup Regulation predict that exposure via incidental ingestion of soil and dust represents 40 to 90% of overall exposure to arsenic-contaminated soils.
- EPA Exposure Guidance and Site-Specific Assessments: Site-specific exposure assessments prepared in accordance with EPA exposure guidance also predict that incidental ingestion of soil and dust is an important exposure pathway. Exposure due to incidental ingestion of soil and dust was estimated to be a significant contributor to overall soil-related arsenic exposure at several Superfund sites (e.g. Coeur d'Alene Basin, Ruston/North Tacoma,Vasquez Boulevard/I-70).
- Soil Ingestion and Exposure Studies: Several researchers have demonstrated that children and adults ingest varying amounts of soil and dust during normal activities (See EPA 2002 for review). Polissar et al. (1990) evaluated the relationships between inorganic urinary arsenic levels and concentrations in various media (e.g. soil, house dust, handwash samples, air, etc.) among children and adults living near a copper smelter in Ruston, Washington. Analysis of the data for young children (0-6 years) indicated that hand-to-mouth activity was the primary source of exposure. However, in a recently-published study, Tsuji et al. (2005) found no significant correlations between speciated urinary arsenic levels and arsenic concentrations in soil and house dust among young children living near a former pesticide manufacturing facility. Tsuji et al. also found no association between activities expected to result in soil exposure (based on responses to survey questionnaire) and urinary arsenic levels.
- Scientific Review Committees: Ecology's procedures for establishing soil cleanup levels are based on the premise that incidental ingestion of soil and dust is an important exposure pathway for children and adults. The MTCA Science Advisory Board reviewed the original cleanup standards (1990) and subsequent amendments (late 1990s/early 2000s) and concluded that the methods and procedures for establishing soil cleanup levels were consistent with current scientific information. In a recent review, a National Research Council (2005) subcommittee concluded that EPA's evaluation of soil-related human health risks at the Coeur d'Alene Superfund site was consistent with EPA guidance documents and current scientific information.
- Uncertainty and Variability: The point estimates developed using the methods and parameters in the MTCA Cleanup Rule appear to provide health conservative exposure estimates in that the point estimates generally fall at the upper end of simulated distributions that take into account the variability in individual exposure parameters. However, the degree of conservatism (as measured by where the point estimate falls within the simulated distribution) may be greater for this pathway than other potential pathways (e.g. dermal contact, homegrown vegetables). Consequently, the screening analyses may overestimate the contribution of soil ingestion relative to other pathways.

SAB Conclusions and/or Requests for Additional Information

The Board addressed this issue when reviewing information on lead-contaminated soils. During that review, the Board concluded there is sufficient scientific evidence to support

Ecology's conclusion that incidental ingestion of soil and dust is an important pathway of exposure for young children (Summary of March 18, 2004 Science Advisory Board Meeting).

Background Information

Ingestion of arsenic-contaminated soil is a potential source of arsenic exposure. This pathway is considered particularly important for infants and young children because of their crawling and activity patterns and the greater likelihood that they will put their hands or other objects into their mouths. Adults may also ingest soil particles that adhere to their hands, food or other objects (e.g. cigarettes). However, available studies indicate that soil ingestion rates for adults not involved in activities with intensive soil contact (i.e. occupational gardening, construction work) are lower than those for children. Estimates of incidental soil ingestion do not take into account pica behavior (compulsive eating of non-nutritive substances) which can involve the ingestion of much larger amounts of soil.

Ecology's procedures for establishing soil cleanup levels are based on the premise that incidental ingestion of soil and house dust as an important exposure pathway for contaminated soils. Using the procedures in the MTCA rule and EPA guidance materials, Landau Associates (2003d, e, f, g) estimated lifetime average daily doses (LADDs) and average daily doses (ADDs) associated with exposure to arsenic-contaminated soils in several common exposure scenarios (e.g. residential, schools, child care facilities and parks). Based on the results from these analyses, arsenic exposure resulting from soil ingestion is predicted to be 40-90% of overall exposure to arsenic-contaminated soils. Table 15 summarizes the LADD values calculated by Landau Associates for residential properties and schools. Similar relationships were observed when comparing predicted ADD for the four pathways.

Table 15: Comparison of Relative Contributions of Different Exposure Pathways to Estimates of Soil-Related Arsenic Exposure

	Soil Ingestion		Dermal Contact		Particulate		Home Grown Vegetables	
Evaluation	mg/kg/day	%	mg/kg/day	%	mg/kg/day	%	mg/kg/day	%
Landau (2003) - residential	1.0E-04	40%	2.2E-06	1%	4.2E-09	0%	1.5E-04	59%
Landau (2003) - schools	2.5E-05	94%	1.7E-06	6%	3.7E-10	0%	NA	0%
Ecology (2004) - residential[12]	1.0E-04	79%	6.6E-06	5%	4.2E-09	0%	2.0E-05	16%
Ruston - residential	1.3E-04	58%	6.2E-06	3%	1.8E-06	1%	8.6E-05	39%
Vasquez Blvd/ I-70 - residential	1.0E-04	70%	3.0E-06	2%	2.0E-06	1%	3.8E-05	27%
Coeur d'Alene - residential	9.8E-05	60%	1.1E-05	7%	1.0E-07	0%	5.4E-05	33%

[12] Ecology modified some the assumptions in the Landau Associates (2003d) analysis based on the SAB's review of the materials on lead-contaminated soils and more recent studies. There are three main differences between the Landau analysis and Ecology's modified analysis: (1) use of a dermal absorption fraction of 3% instead of 1%; (2) use of region-specific particulate emission factors (PEF) to predict particulate levels; and (3) use of procedures and assumptions of evaluating exposure resulting from consumption of homegrown vegetables.

Site-specific exposure assessments prepared in accordance with EPA exposure guidance also predict that incidental ingestion of soil and dust is an important exposure pathway. Table 15 summarizes the LADD values calculated by EPA or its contractors for several Superfund sites with arsenic-contaminated soils. Exposure due to incidental ingestion of soil and dust was predicted to be an important contributor to overall exposure at the Coeur d' Alene Basin Superfund site (60%), Vasquez Boulevard/Interstate 70 Superfund site (70%) and the Ruston/North Tacoma Superfund site (58%). A National Research Council (2005) committee recently completed a review of EPA's evaluation of soil-related human health risks at the Coeur d'Alene Superfund site. Much of the committees' review focused on lead-contaminated soils. With respect to arsenic, the committee concluded that EPA followed guidance for determining human health risks and that EPA's use of the model-based risk estimates to support decisions on remedial actions was appropriate in the absence of human data. However, the committee recommended that EPA continue to support research on biomarkers of human arsenic exposure in order to strengthen future exposure evaluations.

There are several sources of uncertainty and variability that complicate the interpretation of the modeling results for the soil ingestion pathway. These include:

- **Uncertainty and Variability in the Amount of Arsenic in Soils and Dust:** There is limited information available on arsenic soil concentrations in many parts of the state. Available information indicates that soil concentrations are highly variable which complicates efforts to define exposure point concentrations that accurately represent soil concentrations in yards and playgrounds. Additional sources of uncertainty and variability include:
  - **Arsenic Enrichment in Smaller Soil Particles**: Most of the information on arsenic concentrations in Washington soils is reported for the 2 mm size fraction. However, studies indicate that exposure to soil via ingestion occurs mainly through the finer soil particles that are more likely to adhere to children's hands. Finer soil particles tend to have higher concentrations than coarse soil particles and enrichment factors[13] ranging from 1.1 to 3 have been reported in various studies[14]. Bioavailability also tends to increase with smaller soil particles. Exposure estimates based on the 2 mm size fraction may underestimate the potential exposure resulting from the incidental ingestion of soil and dust.
  - **Dust Concentrations**: Ecology does not routinely collect information on the concentrations of hazardous substances in house dust. The methodology used to estimate exposure resulting from incidental ingestion of soil and dust is based on the assumption that house dust and soil concentrations are equal. Asarco and others have argued that this over-predicts arsenic exposures because house dust typically has lower concentrations of metals than soil (Aldrich, 1999).[15] However, Glass and SAIC (1992) analyzed the entire data set (120 households) from the

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[13] For purposes of this discussion paper, enrichment factors are defined as the ratio of contaminant concentrations in finer fractions (< 250 um) to contaminant concentrations in soil samples with wider range of soil particle sizes (< 2 mm).

[14] EPA (2001b) collected soil and dust samples from homes at the Vasquez Boulevard/I-70 site near Denver CO and found that arsenic concentrations in dust were approximately 1.1 times higher than soil lead concentrations from the same property.**[add information from Exposure Pathways Study/Vanderbilt Study on Vashon/information on lead].**

[15] Asarco also noted that Ecology has used dust/soil ratios of 0.45 to 0.7 when establishing lead cleanup standards.

Exposure Pathways Study conducted by the University of Washington (Polissar, et al. 1987) and found that arsenic concentrations in vacuum bag dust were higher than soil concentrations at 67 of the 120 households included in the study. The median value for the dust-to-soil ratio was 1.15. Glass and SAIC also performed linear and log-log regression analyses on both the full data sets (120 matched sets) and results from the Ruston census tract (25 matched sets). Based on these regression analyses, they concluded that assuming house dust concentrations are equal to soil concentrations may reflect overestimates when soil concentrations are high and underestimates when soil concentrations are low. The break point between high and low soil concentrations ranged from 112 mg/kg to 443 mg/kg depending on which regression method and data set was used. The Exposure Pathways Study includes matched soil and dust data from 17 households on Vashon Island where soil concentrations are at or below levels being considered as "moderate" concentrations. Dust-to-soil ratios in those households ranged from 0.15 to 37.29[16]. TerraGraphics et al. (2001) measured arsenic concentrations in samples from yard soils, floor mats in home entrances and vacuum bag samples. They found that concentrations of arsenic in floor mat samples were significantly enriched relative to yard soil concentrations. They also found significant dilution between floor mat concentrations and vacuum bag concentrations and, consequently, vacuum bag concentrations were not significantly different than yard soil concentrations. However, the scatterplots of dust vs soil prepared by TerraGraphics did not show a clear relationship between yard soil and dust concentrations. Some type of dilution effect is consistent with the results from Trowbridge and Burmaster (1997) who compiled information on 12 rare earth elements from studies where concentration data was available for both soil and dust. Using information from those studies, Trowbridge and Burmaster produced 26 estimates of a dust to soil ratio ranging from 0.2 to 0.92. The authors concluded that a lognormal distribution fit the data very well (r2 = 0.9729) with an arithmetic mean and standard deviation of 0.445 and 0.1687, respectively. In general, the assumptions implicit in the MTCA methods may over-estimate or under-estimate exposure.

- **Uncertainty and Variability in the Frequency and Amount of Soil Ingested by Children**: Exposure estimates are heavily dependent on the assumptions made regarding the frequency and amount of soil ingested by children. The screening assessment summarized below indicates that variability in soil ingestion rates is the most important contributor to overall variability in exposure estimates.

  - **Incidental Soil/Dust Ingestion Rate (SIR)**: The amount of soil ingested by children is influenced by several factors including age, activity patterns and accessibility to soil and dust. Estimates for young children (ages 2 -6) range from 39 to 271 mg/day. However, there are several sources of uncertainty in the estimates derived from individual studies[17]. The screening level analyses were

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[16] A limited regression analysis performed with the 16 matched samples collected on Vashon Island during the Exposure Pathways Study suggest predict that dust concentrations will equal soil concentrations at soil concentrations between 40 and 50 ppm (depending on whether soil concentrations below 10 mg/kg are included in the analysis). The linear model provides the best fit (r-squared value = @.62) when three soil samples below 10 mg/kg were excluded from the analysis.

[17] DEQ (1998) summarized a range of factors that contribute to uncertainty in estimated soil ingestion rates:

performed using the soil ingestion rate (200 mg/day) specified in the MTCA rule and current EPA guidance (EPA, 1997a, 2002a). This value is intended to represent an upper-bound value (90^{th} – 95^{th} percentile). Recent re-analyses of the data from the Amherst MA and Anaconda MT studies (Stanek and Calabrese, 2000; Stanek et al. 2001) suggest that the upper percentile estimates derived from short study periods (7 days) may overestimate the average 95^{th} percentile for longer periods of time. Several individuals and organizations have proposed the use of probability density functions to account for the variability in soil ingestion rates (Burmaster and Thompson, 1991; DEQ, 1998; Stanek and Calabrese, 2001; Stern, 1994)[18]. Table 16 summarizes several of the approaches used by state and federal agencies.

Table 16: Examples of Distributions Developed to Characterize Variability in Child Soil/Dust Ingestion Rates

Source	Distribution
EPA Region VIII[19]	Lognormal (AM = 100; SD = 53)
EPA Office of Pesticide Programs	Lognormal (M = 60, SD = 80, UB = 500)
Oregon Department of Environmental Quality[20]	Lognormal (mean of natural logarithms = 4; standard deviation of natural logs = 0.3, LB = 0 and UB = 480)
Stern (New Jersey Department of Environmental Protection)[21]	Triangular (50, 100, 200)

- **Pica Behavior**: Studies have shown that some children intentionally ingest soil at rates far higher than those associated with incidental exposure. ATSDR recommends using a soil ingestion rate of 5,000 mg/day to characterize potential soil pica exposure associated with short-term exposures. However, there is limited data available on the prevalence of pica behavior and soil ingestion rates associated with such behavior (particularly from a chronic exposure standpoint).

Sample populations are small and/or localized and, therefore, may not be representative of the general population of similarly aged individuals; the age range of the subjects is restricted (1-7 years old, except for a single study of six adults) and, therefore, may not be representative of the population at large; studies have been short-term (3-8 days), due largely to the costly, labor-intensive and logistically complex nature of these studies; seasonal variation in soil ingestion may bias results; correction may or may not be made for tracer ingested from sources other than soil (*e.g.* food, medicines, toothpaste); calculations of tracer quantities in food incorporate any error or uncertainty in the measurement of the amount of food consumed; attempts to distinguish contributions from soil versus house dust have yielded conflicting results; collection of input (food and nonfood tracer sources) and output (feces, urine) may be incomplete; the tracer methodology has not been validated using children as subjects.

[18] Other analysts have developed distributions to characterize the variability in soil ingestion rates. The Oregon DEQ guide on probabilistic risk assessment includes a probability density function based on analyses by Burmaster and Thompson (1991) and Stanek and Calabrese (1995). Stern (1994) appears to have based the selection of a triangular distribution (and the distribution parameters) on information in Calabrese et al. (1989) and Davis et al. (1990).

[19] EPA Region VIII used several approaches to characterizing the soil/dust ingestion rates as part of the risk assessment for the Vasquez Boulevard/I-70 site outside Denver CO. One approach involved fitting a lognormal distribution selected to match EPA guidance values of 100 mg/day and 200 mg/day for CTE and RME exposures.

[20] The Oregon Department of Environmental Quality (DEQ) guidance document on probabilistic risk assessment includes a probability density function based on data from Calabrese et al. (1989) and Davis et al. (1990).

[21] Stern (1994) also based the selection of a triangular distribution (and the distribution parameters) on information in Calabrese et al. (1989) and Davis et al. (1990).

Battelle (1998a) reviewed the scientific literature available on this issue to support EPA's efforts to define lead-based paint hazards under the Toxics Substances Control Act and reached the following conclusions: (1) prevalence of soil pica, exclusive of paint pica, is most likely between 10 and 20 percent in young children[22]; (2) soil pica behavior is episodic in nature[23]; and (3) estimates of the amount of soil ingested during pica estimates vary widely among mass balance studies, from 500 to 13,000 mg/day[24]. Using the assumptions on soil pica frequency and ingestion rates developed by Battelle (1998a) with the assumption that a child ingests 200 mg/day on days when not displaying pica behavior results in average daily intakes ranging from 280 – 340 mg/day (averaged over 365 days).

- **Fraction Ingested as Soil (Fs)**: The risk assessment model included in the MTCA Cleanup Regulation does not distinguish between the amount of exposure due to soil and that due to household dust. However, the relative amount of exposure derived from the soil and dust are likely to vary between children, seasons and activity patterns. Consequently, this is a source of uncertainty and variability that becomes an issue when dust concentrations are not equal to soil concentrations. There are several commonly cited references in the literature. The recommended soil ingestion rates in the *Child-Specific Exposure Factors Handbook* (EPA, 2002a) reflects a 70 percent contribution from soil and 30 percent from dust. When evaluating exposure to lead-contaminated soils, EPA typically assumes that 45 percent of the combined soil/dust ingestion is from soil. There have also been several attempts to characterize the variability in this ratio.[25] A screening level analysis prepare to evaluate how variations in various input parameters influences estimates of lead uptake in children suggests this factor does not significantly contribute to the overall variability in exposure estimates for this pathway.

- **Uncertainty and Variability in the Amount of Soil-Bound Arsenic that is Absorbed into the Blood Stream**. Exposure estimates are heavily dependent on the

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[22] Battelle (1998a) concluded that the Boston and Baltimore portions of the USLADP provide the best estimates of soil pica behavior in the absence of paint pica (14.4 and 16.3 percent, respectively).

[23] Battelle (1998a) concluded that the frequency of soil pica episodes depends on many factors, including climate, access to bare soil, socioeconomic standing, age of child and parental supervision. In one study of 12 children identified by their parents as being pre-disposed to pica for soil, only one child displayed soil pica during the two week observation period (Calabrese et al., 1997). Only one other study estimated annual rates for pica episodes (Stanek and Calabrese, 1995). This study, suggested that 33 percent of children would ingest more than 10 grams of soil on 1-2 days per year, and that 16 percent of children are expected to ingest more than 1 gram of soil on 35-40 days per year.

[24] The average daily ingestion over a year, however, may be much lower. Assuming the frequencies estimated by Stanek and Calabrese (1995), children who ingest 15 grams of soil on 1-2 days per year and 50 mg/day on remaining days would have an average daily soil intake of 132 mg/day over the course of a year. Children who ingest 1.5 grams of soil on 40 days per year and 50 mg/day on remaining days would have an average daily soil intake of 209 mg/day. (Battelle, 1998a, p. 158).

[25] EPA (2001c) used a triangular distribution (0.1, 0.45, 0.8) to characterize the fraction of combined soil/dust ingestion that is ingested as soil. Stern (1994) defined F_s (referred to as P_1 – the fraction of the soil/soil-derived dust ingestion attributable to outdoor soil) as the product of (1) the fraction of waking hours spent outdoors ($T_{outdoors}$) and the (2) ratio of the rate of the outdoor soil ingestion to the combined soil + indoor dust ingestion rate ($I_{soil}/IR_{soil + dust}$). Stern characterized each of these parameters as a triangular distribution ($T_{outdoors}$) or as a product of several triangular distributions ($I_{soil}/IR_{soil + dust}$).

assumptions made regarding the amount of soil-bound arsenic that is absorbed into the blood stream.

- **Relative Bioavailability**: The exposure model incorporated into the Model Toxics Control Act Cleanup Regulations includes a default assumption that 100% of soil bound arsenic is bioavailable. The regulation provides the flexibility to use alternate values based on chemical-specific information and recent studies and scientific reviews have observed that soil-bound metals are typically less bioavailable than soluble forms present in drinking water (NRC, 2003; NEPI, 2001). However, White (1999) reviewed the available literature and concluded there was insufficient information to justify the use of an alternate value when establishing soil cleanup levels for the Everett Smelter site. EPA has used site-specific GI absorption factors to characterize human exposure and health risks at several Superfund sites: Coeur d'Alene River Basin (60%); Vasquez Boulevard/ Interstate 70 (42%); and Ruston/North Tacoma (80%). EPA Region X Interim Guidance identifies a range of 60% to100%.

- **Soil Aging Effect**: NRC (2003) states that "...[a]n important aspect governing the bioavailability of solid-phase contaminants is time. With aging, a contaminant is generally subject to transformations that yield a more stable solid-associated compound. This in turn leads to a decrease in the bioavailability of the contaminant with increased reaction time in both soils and sediments..." (p. 148). This analysis is focused on releases of arsenic that occurred 20-100 years in the past. Consequently, it is likely that some amount of transformation has occurred. In general, such transformation would tend to reduce (to an unknown extent) the bioavailability of arsenic in soils. As part of the sensitivity analysis for the Ruston/North Tacoma Superfund site, Glass and SAIC (1992) evaluated the potential impacts on estimated lifetime average daily doses using different assumptions on the amount of degradation of arsenic in soils. This analysis provides a general idea on the potential effects of soil aging if one equates soil aging/reduced bioavailability with degradation. The estimated LADDs ranged from 33% (soil half-life of 7 years) to 82% (soil half-life of 50 years) relative to the estimated LADD based on no soil degradation. In general, soil aging effects on bioavailability are expected to be less for the soil ingestion pathway (due to the high pH levels encountered in the stomach) than other pathways (dermal contact and ingestion of homegrown vegetables where the chemical reactions may reduce the uptake of arsenic into plants).

A screening level assessment was conducted in order to gain a sense of (1) the variability in the arsenic exposure estimates generated by the use of the parameters specified in the MTCA rule and EPA guidance and (2) how the variability in individual input parameters contributes to the overall variability in exposure estimates. With this approach, probability distributions are used as inputs to the exposure model in place of the point estimate values. In this analysis, computer simulation techniques ("Monte Carlo analysis" using the Crystal Ball 2000® software program) were used to combine probability distribution functions for several of the exposure parameters[26] with point estimates for the remaining parameters[27] in the

[26] It was assumed that there are not significant correlations among the parameters characterized by probability distributions.

exposure equation with point estimates for the remaining parameters. Figure 3 describes the exposure model used to estimate arsenic exposure resulting from incidental ingestion of soil and dust[28]. Table 16 summarizes the distributions and point estimates used in this analysis.

Figure 3: Modified Soil/Dust Ingestion Equation Used to Evaluate Variability in Average Daily Dose (ADD) Estimates

$$ADD = \frac{(Cs*SEF*SIR*AbS*EF)(F_s + (M_{SD}*(1-F_s)))}{BW*UCF}$$

Where:

ADD	=	Average Daily Dose (ug/kg/day)
AbS	=	Absorption fraction (unitless)
BW	=	Body weight (kg)
Cs	=	Soil arsenic concentration (mg/kg)
EF	=	Exposure frequency (unitless)
F_s	=	Fraction ingested as soil (unitless)
M_{SD}	=	Mass fraction of outdoor soil to indoor dust (unitless)
SEF	=	Soil/dust enrichment factor (unitless)
SIR	=	Soil/dust ingestion rate (mg/day)
UCF	=	Unit conversion factor (1,000,000 mg/kg)

Table 16: Point Estimates and Distributions Used to Evaluate Variability in Soil/Dust Ingestion Exposure Estimates

Parameter	Point Estimate	Distribution
Absorption Fraction (AbS)	1.0	Triangular (0.6, 0.8, 1.0)
Body Weight (kg)	16	Lognormal (LM = 2.6; LSD = 0.11; UB = 19)
Soil Arsenic Concentration (C_S)	100	Lognormal (AM = 100; SD = 50; UB = 500)
Exposure Frequency (EF_s)	1	
Fraction Ingested as Soil (F_s)	0.45	Triangular (0.1, 0.45, 0.8)
Mass Fraction of outdoor to indoor soil ($_{MSD}$)	0.70	Lognormal (M = 0.445; SD = 0.1687; Range = 0.2 – 0.92)
Soil/dust Enrichment Factor	1	Triangular (1.0, 1.2, 3.0)
Soil/dust ingestion rate (SIR)	200	Lognormal (M = 60, SD = 80, UB = 500)

The Monte Carlo analysis was performed using was performed using 1000, 5000 and 10,000 simulations. The results based on 5000 and 10,000 simulations were very similar.

[27] The results are based on 10,000 Monte Carlo runs. This was found to be a sufficient number of runs to provide a stable output.

[28] The exposure model is a modified version of the standard exposure equation in the MTCA Cleanup Regulation (Figure 1). The following modifications have been made to allow consideration of the variability in several parameters: (1) the exposure duration and averaging times have been removed because they cancel each other out in the ADD calculations; (2) an additional parameter (soil/dust enrichment factor) has been included to allow consideration of the potential enrichment of arsenic in smaller soil particles; and (3) additional parameters have been included to characterize the relationships between arsenic concentrations in soils and soil-derived house dust.

The results of the computer simulation (based on 10,000 simulations) are summarized in Tables 17 and 18. Table 17 indicates that the variation in exposure estimates for this pathway is primarily due to variability in the parameter used to characterize soil ingestion rate. Table 18 indicates that the MTCA point estimate falls near the 95th percentile value of the simulated distribution of ADD estimates.

Table 17: Contribution to Variance in LADD Estimates for Incidental Soil/Dust Ingestion

Parameter	% Contribution	
	Cs = 100	Cs = PDF
Soil Ingestion Rate	90 %	77 %
Soil Concentration	NA	15 %
Soil/dust enrichment factor	6 %	5 %
GI Absorption Factor	1 %	@ 1%
Fraction Ingested as Soil	1 %	@ 1%
Soil/Dust Conversion Factor	1 %	@ 1%
Child body weight	1 %	@ 1%

Table 18: Estimated Average Daily Doses for Soil/Dust Ingestion Pathway at Soil Concentration of 100 ppm (mg/kg/day)

	ADD **(Cs = 100)**	**ADD** **(Cs = PDF)**
MTCA Point Estimate	1.3E-03	1.3E-03
Mean of Simulated Distribution	4.3E-04	4.2 E-04
50th	2.4 E-04	2.1 E-04
75th	5.1 E-04	4.8 E-04
90th	9.6 E-04	9.5 E-04
95th	1.4 E-03	1.4 E-04
Maximum of Simulated Distribution	1.8 E-02	1.6 E-02
Standard Deviation	6.0 E-04	7.1 E-04
Ratio of 90th Percentile/10th Percentile	15	@ 20
Percentile for MTCA Point Estimate	@ 95th	@ 95th

Dermal Exposure to Arsenic-Contaminated Soils

Question #5: Is the assumption that dermal contact with arsenic-contaminated soils represents an important exposure pathway for children & adults consistent with current scientific information?

Ecology Rationale

Ecology has concluded that dermal contact is a complete pathway. Although metals generally have limited ability for absorption through the skin, Ecology has concluded that this pathway could be an important contributor to overall exposure to arsenic-contaminated soils in some situations. This conclusion was reached after considering the following factors:

- Results of Screening Level Analyses: Screening level analyses performed using the methods and assumptions in the MTCA Cleanup Regulation predict that exposure via dermal represents 1 to 10% of overall exposure to arsenic-contaminated soils.
- EPA Exposure Guidance and Site-Specific Assessments: Site-specific exposure assessments prepared in accordance with EPA exposure guidance have reached different conclusions on the importance of the dermal contact pathway. For example, exposure due to dermal was estimated as part of the assessments of exposure to arsenic-contaminated soils prepared for the Coeur d'Alene Basin site (7%) and the Ruston/North Tacoma site (3%). However, EPA (2001) concluded that dermal contact was an insignificant pathway relative to incidental soil ingestion at the Vasquez Boulevard/Interstate 70 site.
- Scientific Literature on Dermal Contact and Absorption of Arsenic: Several studies are available demonstrating that children and adults get soil and dust on their skin during normal activities (see EPA 2002 for review) and that varying amounts of arsenic can be absorbed through the skin.
- Scientific Review Committees: Ecology used the methods and assumptions in the MTCA rule to characterize potential exposure resulting from dermal contact with arsenic-contaminated soils. The MTCA Science Advisory Board reviewed the amendments dealing with dermal contact exposure and concluded that the methods and procedures were consistent with current scientific information. In a recent review, a National Research Council (2005) committee concluded that EPA's evaluation of soil-related human health risks at the Coeur d'Alene Superfund site (including EPA's consideration of dermal contact) was consistent with EPA guidance documents and current scientific information.
- Uncertainty and Variability: The point estimates developed using the methods and parameters in the MTCA Cleanup Rule appear to provide health conservative exposure estimates in that the point estimates generally fall at the upper end of simulated distributions that take into account the variability in individual exposure parameters. However, the degree of conservatism (as measured by where the point estimate falls within the simulated distribution) for this pathway may be less than other potential pathways (e.g. incidental ingestion soil and dust). Consequently, the screening analyses may underestimate the contribution of dermal contact relative to other pathways.

SAB Conclusions and/or Requests for Additional Information

The Science Advisory Board has not discussed this issue in the context of arsenic-contaminated soils. However, the Board agreed with Ecology's conclusions that (1) dermal absorption from lead-contaminated soils is limited and the use of a dermal absorption factor of 0.1% is a reasonable approach for evaluating exposure and (2) dermal contact with lead-contaminated soils does not represent a significant source of exposure relative to other potential pathways (Summary of May 28 Science Advisory Board meeting).

Background Information

Children and adults get soil particles on their skin while working or playing and contaminants present in soils may be absorbed into the body through the skin. The nature and extent of exposure to arsenic via this pathway is influenced by several factors including: (1) soil matrix (e.g. soil type, size fraction, moisture) (2) contaminant bioavailability; (3) child and adult behavior. Dermal contact is considered to be a complete pathway and could be an important contributor to overall exposure to arsenic-contaminated soils in some situations.

The MTCA rule identifies dermal contact as an important exposure pathway for contaminated soils – particularly for organic compounds. Using the procedures in the MTCA rule and EPA guidance materials, Landau Associates (2003d, e, f, g) estimated lifetime average daily doses (LADDs) and average daily doses (ADDs) associated with exposure to arsenic-contaminated soils in several common exposure scenarios (e.g. residential, schools, child care facilities and parks). Table 15 (page 34 in previous section) summarizes the LADD values calculated by Landau for residential properties (dermal contact is estimated to contribute @ 1 percent of overall soil-related exposure) and schools (dermal contact is estimated to contribute @ 6 percent of overall soil-related exposure). Using a dermal absorption fraction of 3% and a GI absorption factor of 80%, Ecology estimated that dermal contact contributed approximately 5% of the overall exposure associated with arsenic-contaminated soils for a residential exposure scenario.

Site-specific exposure assessments prepared in accordance with EPA exposure guidance have reached different conclusions on the relative importance of the dermal contact pathway. EPA considered this pathway in the quantitative portion of the exposure assessments prepared for the Coeur d'Alene Basin Superfund site and the Ruston/North Tacoma Superfund site. EPA estimated that dermal contact contributed 7% (Coeur d'Alene) and 3% (Ruston/North Tacoma) of the overall exposure to arsenic-contaminated soils at these two sites. However, EPA (2001) concluded that dermal contact was in insignificant pathway relative to incidental soil ingestion at the Vasquez Boulevard/Interstate 70 site.

There are several sources of uncertainty and variability that complicate the interpretation of the modeling results for the dermal contact pathway. These include:

- **Uncertainty and Variability in the Amount of Arsenic in Soils and Dust:** There is limited information available on arsenic soil concentrations in many parts of the state. Available information indicates that soil concentrations are highly variable which complicates efforts to define exposure point concentrations that accurately represent soil concentrations in yards and playgrounds. Similar to the soil ingestion pathway, questions also arise due (1) uncertainties on the concentrations of arsenic in the finer soil fractions that are more likely to adhere to the skin surface and (2) uncertainties on the relationships between dust and soil concentrations and how those relationships vary in different exposure situations. As noted above, the issue of soil aging discussed by NRC (2003) may be more relevant to evaluating dermal contact exposure than situations where soil is ingested and subjected to the high pH levels in the stomach.

- **Uncertainty and Variability in the Frequency and Amount of Soil Contact**: Dermal contact with contaminated soils is influenced by a wide range of factors including activity, soil characteristics and area of the body coming into contact with soil. The methods for estimating dermal contact rates in the MTCA rule are based on exposure parameters (soil adherence and exposed surface area) that do not explicitly take into account such variations (i.e. the default values for soil adherence and exposed surface area are not linked to particular activities and/or body parts). Current EPA guidance (EPA 2002a) for characterizing dermal exposure recommends using a combination of (1) activity-specific soil adherence factors for different body parts (e.g. face, hands, arms, legs, feet, etc) and (2) the surface area for the entire body part (as opposed to estimates of the exposed portions of those parts of the body). Table 19 illustrates the range of dermal contact rates (measured as the product of the adherence factor surface areas for different body parts) that might occur in different exposure situations. For many activities/exposure scenarios, it appears that the MTCA methodology provides a higher estimated contact rate than would be obtained using the activity-specific information in EPA (2002a). [Note: comparisons were made using mean values for adherence factors – not upper bound values]. One exception is where children are playing in wet soils or mud. For such situations, the recommended soil adherence factor is 2-4 orders of magnitude higher than the values for other activities.

Table 19: Relative Dermal Contact Rates Using Recommendations in Child Specific Exposure Factors Handbook (EPA, 2002a)[29]

Exposure Scenario	$\sum AF * SA$
Indoor children	23
Daycare children (indoors & outdoors)	200
Soccer	137
Children playing in mud	82,665
Theoretical soil "monolayer"[30]	17,600
General exposure (MTCA Rule)	440

- **Uncertainty and Variability in the Amount of Soil-Bound Arsenic that is Absorbed into the Blood Stream**. Exposure estimates depend on the assumptions made regarding the amount of soil-bound arsenic that is absorbed across the skin surface into the blood stream. Although dermal contact with metals represents a potential exposure pathway, the relatively low lipid solubility of most metals is

[29] The activity-specific product of dermal adherence factor and skin surface was calculated using information from Chapter 8 of the Child-Specific Exposure Factors Handbook (EPA, 2002a). The product (SA*AF) of each activity was calculated in two steps. First, estimates of surface areas for various body parts (e.g. hands, arms, etc) were calculated using the 95th percentile body surface area for males age 3-4 years of age (0.764 m^2) in Table 8.1 and the percentages of total body surface area for various body parts (Table 8.3). For example, the mean percentage for hands (6.07) for 3-4 year olds was multiplied by the total body surface area to obtain an estimate for hand surface area (46 cm^2). These calculated surface areas were then multiplied by the appropriate adherence factors in Table 8.8. For example, Table 8.8 lists two soil adherence factors for daycare children playing indoors and outdoors (Daycare kids 1a and 1b). The average of these two values was multiplied by the calculated hand surface area to obtain an SA*AF value for hands for that activity. Similar products were calculated for arms, legs and feet. The products (SA*AF) for various parts of the body were then summed to provide activity-specific values (sum of activity-specific SA*AF values = 200).

[30] EPA (1992) noted that "...[s]ome investigators (Yang et al. 1989) have postulated that soil absorption occurs only from a "monolayer" of soil, and that the absorbed is independent of the amount of soil on the skin exceeding the monolayer. This monolayer has not been well defined but could not be interpreted as a single layer of soil particles. Assuming tightly packed 100 um particles, approximately 10,000 particles would fit on 1 cm2 and weigh 8 mg/cm2 (assuming particle density of 1,500 mg/cm3)...."

generally thought to limit absorption through the skin far more than for more lipid-soluble organic chemicals. However, the extent to which soil-bound arsenic is absorbed across the skin surface depends on a number of factors including soil properties (particle size, organic carbon content, oxides, moisture), area of the body, condition of the skin and length of time soil adheres to the skin surface. The MTCA default value (0.03) used to characterize this parameter are based on results from Wester, et al. (1993). In general, this has been considered to be an upper-bound estimate for dermal absorption of soil-bound arsenic. However, the FIFRA Scientific Advisory Committee recently noted that "...the current default dermal availability used by the Agency (a Beta distribution with mean and median of about 3% per 24 hours) falls closer to the low end of the 2-8% range of availability of inorganic arsenic that could be derived from the 1993 and 2003 Wester et al. studies if correction by intravenous response is assumed appropriate for dermal application of inorganic arsenic..." (EPA, 2004, p. 54).

A screening level assessment was conducted in order to gain a sense of the variability surrounding the exposure estimates produced using standard risk assessment methods and how variability in individual input parameters contributes to the overall variability in exposure estimates. For purposes of this evaluation, dermal absorption was considered to be a variable parameter (as opposed to an uncertain one). The relative contribution of each parameter was assessed by performing a Monte Carlo Analysis with Crystal Ball 2000® software. The dermal exposure model used to estimate arsenic exposure is shown in Figure 4[31]. Table 20 lists the distributions and point estimates used in the analysis.

Figure 4: Dermal Exposure Equation

$$ADD = \frac{C_s \cdot (SA/BW) \cdot AF \cdot ABS_d \cdot EvF \cdot EF \cdot UCF_2}{UCF_1}$$

Where:

ADD_D	=	Average daily dose (mg/kg/day)
ABS_D	=	Dermal absorption fraction (unitless)
AF	=	Soil adherence factor (mg/cm^2-event)
Cs	=	Soil arsenic concentration (mg/kg)
EvF_D	=	Event frequency (events/day)
EF_D	=	Exposure frequency (unitless)
SA/BW	=	Surface area/body weight (cm^2)
SEF	=	Soil/Dust enrichment factor (unitless)
UCF	=	Unit conversion factor (10^6 g/kg)
UCF2	=	Unit conversion factor (10^{-4} m^2/cm^2)

[31] The dermal exposure model used in this assessment is a modified version of the model in the MTCA rule. The primary differences are (1) the use of a surface area/body weight ratio instead of separate entries for dermal surface area and child body weight and (2) use of an additional factor to account for the potential enrichment of arsenic in smaller soil particles.

Table 20: Point Estimates and Distributions Used to Evaluate Variability in Dermal Contact Exposure Estimates		
Parameter	Point Estimate	Distribution
Absorption Fraction (unitless)	0.03	Lognormal (AM = 0.03, SD = 0.02; range = 0 to 0.1)
Adherence Factor (mg/cm^2 - event)	0.2	Lognormal (GM = 0.11; GSD = 2.0)
Soil Arsenic Concentration (mg/kg)	100	
Event Frequency (event/day)	1	
Exposure Frequency (unitless)	1	
Surface Area/Body weight (m^2/kg)	0.064	Lognormal (AM = 0.0641, SD = 0.0114, range = 0.0421 – 0.1142) [32]
Soil/Dust Enrichment Factor	1	Triangular (1, 1.2, 3)

Table 21 indicates that the variation in exposure estimates for this pathway is primarily due to the variability in soil adherence and the dermal absorption factor (> 90%). Table 22 indicates that the point estimate falls at approximately the 60th percentile (assuming arsenic enrichment in smaller soil particles) and the 80th percentile (assuming no enrichment) value of the simulated distribution of arsenic exposure levels.

Table 21: Contribution to Variance in Average Daily Dose for Dermal Exposure		
	#1	#2
Soil Adherence Factor	52 %	55 %
Dermal Absorption Factor	39 %	42 %
Soil/Dust Enrichment Factor	6%	--
Surface Area/Body Weight	3%	3 %

Table 22: Estimated Average Daily Dose for Dermal Contact at Soil Concentration of 100 ppm (mg/kg/day)		
	Estimated ADD (with soil enrichment factor)	**Estimated ADD** (without soil enrichment factor)
MTCA Point Estimate	8.3 E-05	8.3 E-05
Mean of Simulated Distribution	1.0 E-04	5.6 E-05
50th	6.3 E-05	3.7 E-05
75th	1.2 E-04	7.0 E-05
90th	2.1 E-04	1.2 E-04
95th	3.1 E-04	1.7 E-04
Maximum of Simulated Distribution	1.6 E-03	7.2 E-04
Standard Deviation	1.2 E-04	6.2E-05
Ratio of 90th Percentile/10th Percentile	11.5	10.9
Percentile Value for MTCA Point Estimate Value	@ 60th	@ 80th

[32] The lognormal distribution for surface area/body weight ratio (Lognormal (AM = 0.0641; SD = 0.0114; range (0.0421 – 0.1142).) was obtained from the EPA Child-Specific Exposure Factors Handbook (0 – 2 years).

Arsenic Exposure from Inhalation of Re-Suspended Soil and Dust

Question #6: Is the assumption that inhalation of wind-blown dust is a minor contributor to overall arsenic exposure consistent with current scientific information?

Ecology Rationale

For purposes of this evaluation, Ecology believes that inhalation of wind-blown dust is a complete pathway, but is a minor contributor to overall exposure to arsenic-contaminated soils. In reaching this conclusion, Ecology considered the following factors:

- Screening Level Assessments: Screening level analyses predict that the estimated exposure via inhalation of windblown dust is 100-1000 times lower than the estimated exposure via soil ingestion & dermal contact (Landau Associates, 2003).
- EPA Evaluations at Federal Superfund Sites: The screening results are consistent with recent risk assessments prepared using the methods and assumptions in EPA's exposure guidance documents. Specifically, screening level assessments performed for the Coeur d'Alene River Basin Superfund Site (TerraGraphics et al. 2001) and the Vasquez Boulevard/Interstate 70 Superfund Site (EPA, 2001) concluded that inhalation of windblown dust was a minor contributor to overall exposure.
- Arsenic Exposure Studies: Polissar et al. (1990) evaluated the relationships between inorganic urinary arsenic levels and concentrations in various media (e.g. soil, housedust, handwash samples, air, etc.) among children and adults living near a copper smelter in Ruston, Washington. Analysis of the data for young children (ages 0-6 years) indicated that hand-to-mouth activity was the primary source of exposure. Polissar et al. also concluded that inhalation of ambient air and resuspension of contaminated soil were not important sources of arsenic exposure for children and adults.
- Uncertainty and Variability: The EPA Screening Model is designed to provide a conservative estimate of particulate matter generated by wind erosion of surface soils. However, there are several sources of uncertainty that might reduce the levels of conservatism inherent in the model.

SAB Conclusions and/or Requests for Additional Information

The Board has not discussed this issue with respect to arsenic-contaminated soils. However, the Board concluded that (1) Ecology should consider inhalation of windblown dust when estimating overall lead exposure and (2) the default value used in the EPA lead model provides a conservative approach for evaluating this pathway.

Background Information

Direct measurement of arsenic in windblown dust/resuspended soils were not available for this evaluation. Landau Associates (2003c) estimated levels of lead and arsenic in resuspended soils using two approaches:

- Estimates Based on Particulate Matter (PM_{10}) Monitoring Data: Landau Associates used PM_{10} data obtained from the Spokane County Air Pollution Authority and the Yakima Regional Clean Air Authority and information on soil arsenic concentrations to estimate levels of arsenic in airborne dust. This analysis assumed that arsenic concentrations in soils are similar to those in dust.
- Particulate Emission Factor: Landau Associates used a "particulate emission factor" (PEF) developed by EPA (1996) to estimate the amount of airborne dust that may be suspended

from erosion of surface soil. Under this approach, the reciprocal of the PEF provides an estimate of airborne dust concentrations. Estimates of ambient levels of arsenic are then based on the assumption that arsenic concentrations in soils are similar to those in dust.

Table 23 lists the airborne arsenic concentrations associated with a soil concentration of 100 mg/kg predicted by the two approaches described in Landau Associates (2003c). Landau Associates (2003d, e, f, g) used the equation in Figure 5 to estimate arsenic exposures associated with inhalation of windblown dust. The estimated child RME exposures via this pathway are 3E-07 mg/kg/day (PM_{10} monitoring data approach) and 1E-08 mg/kg/day (PEF approach) at a soil concentration of 100 mg/kg. These exposure estimates are two to four orders of magnitude lower than estimated exposures via soil ingestion/dermal contact (1.1E-04 mg/kg/day) calculated using the equations in the MTCA rule. The relative cancer risk (expressed as the ratio of predicted cancer risks associated with soil ingestion and inhalation of resuspended soils) indicates that the contribution from the inhalation pathway is small in comparison to risks predicted for soil ingestion pathway.

Table 23: Estimated Airborne Arsenic Concentrations, Exposures and Relative Cancer Risks (Based on Soil Arsenic Concentration = 100 mg/kg)

Method Used to Estimate Airborne Arsenic Levels	Estimated Airborne Arsenic Concentration (ug/m3)	Estimated Arsenic Exposure via Inhalation of windblown dust (mg/kg/day)	Relative Exposure (Ratio of Soil Ingestion & Dermal Contact Exposure & Windblown Dust Exposure)	Relative Cancer Risk[33] (ratio of estimated risks due to soil ingestion and inhalation)
PM_{10} Monitoring Data[34]	0.006	3E-07	370	37 - 230
Particulate Emission Factor[35]	0.0002	1E-08	11,000	1,100 – 6,600

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[33] The relative cancer risk depends on the differences between the inhalation slope factor and the oral slope factor. EPA has established an inhalation slope factor of 15.1 mg/kg/day^{-1} for arsenic. Oral slope factors discussed under Issue #1 range from 1.5 to 9.4 mg/kg/day^{-1}.

[34] Landau Associates used information on the maximum PM_{10} dust concentrations from Spokane and Yakima County to calculate an estimated airborne arsenic concentration of $1x10^{-2}$ ug/m^3. Key assumptions include: (1) arsenic concentrations in airborne dust are the same as those in soils; (2) estimated maximum $PM_{2.5}$ concentrations are 60% of maximum PM_{10} concentrations. An additional multiplier (3) was included to account for potential enrichment in windblown dust relative to parent soils. This a high-end estimate used by Stern (1994) to estimate arsenic concentration in household dust derived from outdoor soils. However, it is consistent with the results from the Exposure Pathways Study (Polissar et al. 1990) where the mean arsenic concentrations in the fine fraction collected from personal air samples and indoor air samples were 2-3 times higher than mean arsenic concentrations in the coarse fraction. [NOTE – results for outdoor air were either contradictory (in the Ruston census tract - mean arsenic concentrations in the fine fraction were less than the mean arsenic concentrations in the coarse fraction) or showed smaller differences between the fine and coarse fractions (e.g. Vashon/Maury Island census tract)

[35] Landau Associates used the EPA Screening Model to produce an estimate of airborne arsenic concentrations. This estimate was prepared using the EPA model and the following data and assumptions: (1) a PEF based on regional default values was used to estimate PM_{10} concentrations; (2) PM_{10} concentrations were assumed to be a surrogate for $PM_{2.5}$ levels; (3) average soil arsenic concentrations are 100 mg/kg; and (4) the arsenic concentrations in the smaller airborne particulates are enriched (by a factor of 3) relative to soil concentrations in the parent soil.

The Landau and Ecology screening results are consistent with recent risk assessments prepared using the methods and assumptions in EPA's exposure guidance documents.

- Coeur d'Alene River Basin Superfund Site: TerraGraphics et al. (2001) performed a screening level analysis to identify the exposure pathways to be addressed in the quantitative evaluation of human exposure and health risks at the Coeur d'Alene Basin. TerraGraphics used the EPA Screening Model (EPA 1996) to estimate airborne arsenic concentrations. Using an equation similar to Figure 5 below, TerraGraphics calculated a soil screening level (747 mg/kg) based on a target risk of 10^{-6} for exposure via inhalation of wind-blown dust. This screening level is @ 1000 times higher than the screening value for soil ingestion. Based on the results of the screening level analysis, TerraGraphics did not include the air pathway in the quantitative evaluation of health risks.
- Vasquez Boulevard/Interstate 70 Superfund Site: EPA (2001) used the EPA Screening Model to estimate exposures and risks associated with inhalation of wind-blown dust at the Vasquez Boulevard/Interstate 70 Site in Denver Colorado. EPA concluded that inhalation from airborne particulate matter was a minor contributor to overall arsenic exposure (less than 0.2%) and did not include this pathway in the quantitative evaluation of residential exposure levels.

Figure 5
Exposure Model for Inhalation of Windblown Dust

$$LADD / ADD = \frac{C_s \cdot \left(\frac{F_s}{PEF} \right) \cdot BR \cdot ABS_{inh} \cdot EF \cdot ED}{ABW \cdot AT}$$

Where:

LADD	=	Lifetime average daily dose (mg/[kg-d])
ADD	=	Average daily dose (mg/[kg·d])
ABS_{inh}	=	Inhalation absorption factor (unitless)
ABW	=	Child body weight (kg)
AT	=	Averaging time (yr)
BR	=	Inhalation rate (m^3/d)
C_s	=	Contaminant concentration in soil (mg/kg)
EF	=	Exposure frequency (unitless)
ED	=	Exposure duration (yr)
F_s	=	Fraction of soil contaminated (unitless)
PEF	=	Particulate emission factor (m^3/kg)

Parameter	Units	LADD	ADD
ABW	kg	16	16
ABS_{inh}	unitless	1.0	1.0
AT	yr	75	6
BR	m^3/d	10	10
C_s	mg/kg	Variable	Variable
EF	unitless	1.0	1.0
ED	yr	6	6
F_s	unitless	1	1
PEF	m^3/kg	520,000,000	5,200,000

Ecology analysis and conclusions are based on the assumption that the methods and parameters used in the analysis provide a conservative[36] estimate of exposures resulting from inhalation of windblown dust/re-suspended soils and dust. Confidence in this assumption is strengthened by the fact that EPA and other state agencies[37] are using similar methods when performing screening level analyses. However, there are several sources of uncertainty and variability that complicate the use and interpretation of the results from the screening level analyses:

- Estimates of Particulate Matter Based on Particulate Emission Factor: A key factor in the EPA screening equation is the particulate emission factor (PEF) which represents an estimate of the amount of dust that may be suspended from the soil surface due to wind erosion. The concentration of respirable particulate matter (expressed as PM_{10}) is calculated as the reciprocal of the PEF value. The initial screening analyses prepared by Landau Associates (2003) were based on a PEF value of 4.63×10^9 m^3/kg which produces estimated PM_{10} and airborne arsenic concentrations of 0.2 ug/m^3 and 4×10^{-5} ug/m^3, respectively. However, PEF values vary depending on several factors (e.g. soil moisture, soil type, parcel size etc) and the EPA guidance materials contain information for taking some of those factors into account by varying the Q/C[38] value according to region and parcel size. Table 24 provides a comparison of predicted airborne arsenic concentrations using EPA default regional values applicable to Eastern and Western Washington. The comparison indicates that the use of PEF values based on regional default parameters that more closely reflect conditions in Washington results in estimates of PM_{10} and airborne arsenic concentrations that are 5 to 10 times higher than the estimates based on the national default value. The higher estimates are similar to the default values used by the State of California to evaluate inhalation exposure associated with lead-contaminated soils. Consequently, it appears that some of the assumptions inherent in the use of national default values would under-predict PM_{10} levels for some Washington exposure scenarios. However, as shown in Table 23, exposure estimates based on regional PEF values are still substantially lower than exposure estimates for soil ingestion.

- Estimates of Airborne Arsenic Concentrations Using PM_{10} Monitoring Data: Landau Associate included estimates of airborne arsenic concentrations that were based on PM_{10} concentrations measured at ambient monitoring stations in Spokane and Washington. Specifically, the maximum reported PM_{10} concentration from Spokane and Yakima Counties (100 ug/m^3) was used to estimate $PM_{2.5}$ and airborne arsenic concentrations of 60 ug/m^3 and 1×10^{-2} ug/m^3, respectively. The maximum PM_{10} measurements are based

[36] Ecology Air Quality Program staff working on Washington's policy for addressing situations where air quality standards are exceeded due to natural events (e.g. windblown dust) reviewed the model and underlying assumptions and concluded that the model should produce a conservative estimate of windblown dust. However, they also noted the model is relatively old and the Ecology Air Quality Program currently uses models that enable use of more realistic assumptions

[37] The California Office of Environmental Health Hazard Assessment (OEHHA) recently published the document entitled "Guidance for School Risk Assessment Pursuant to Health and Safety Code Section 901(f): Guidance California. The health risk screening procedures for evaluating the potential exposures due to inhalation of windblown dust incorporate a default dust concentration in outdoor air (1.5 ug/m3) that was derived using the EPA Soil Screening Guidance (EPA, 1996). The California LeadSpread Model used to evaluate lead contaminated soils also uses the EPA screening model to predict airborne lead concentrations associated with windblown dust.

[38] The calculated PEF values are sensitive to the assumptions made regarding the Q/C factor which varies with geographic area and property size.

on concentrations measured during a 24 hour period. A recent report published by the Ecology Air Quality Program summarizes the annual mean $PM_{2.5}$ concentrations for Spokane and Yakima for the years 1999 through 2001. In both areas, annual mean $PM_{2.5}$ concentrations were 8-10 ug/m3. This range is 6-7 times lower than the estimated $PM_{2.5}$ value used in the earlier analysis.

- Enrichment of Arsenic in Finer Soil Fractions: Exposure estimates assume a uniform level of arsenic in soil particles. However, arsenic and other metals are generally present in higher concentrations in smaller soil particles that are more likely to reach the lungs. Polissar et al. (1990) reported that the mean arsenic concentrations in the fine fraction collected from personal air samples and indoor air samples were 2-3 times higher than mean arsenic concentrations in the coarse fraction. [NOTE – results for outdoor air were either contradictory (in the Ruston census tract - mean arsenic concentrations in the fine fraction were less than the mean arsenic concentrations in the coarse fraction) or showed smaller differences between the fine and coarse fractions (e.g. Vashon/Maury Island census tract)

- Windblown Dust Resulting from Mechanical Disturbances: The EPA Screening Model is designed to estimate the amount of exposure resulting from wind-based soil erosion. However, significant amounts of soil might be released into the air as a result of mechanical disturbances (e.g. tilling of soils in agricultural areas, riding bikes or all-terrain vehicles on dirt trails, automobile traffic on dirt roads). The Landau Associates screening estimate based on PM_{10} monitoring data in Yakima and Spokane provides information for evaluating potential for elevated levels due to mechanical disturbances if one conservatively assumes that the measured PM_{10} levels are all attributable to mechanical erosion of contaminated soils. The results of the screening analysis indicate that even under conditions of mechanical disturbance, exposure resulting from the inhalation of airborne arsenic is still likely to be quite low relative to soil ingestion exposure.

Table 24: Range of Predicted PM_{10} and Arsenic Concentrations Predicted Using Fugitive Dust Screening Model in EPA (1996)

	Q/C[39]	PEF	PM_{10}	Airborne Arsenic
	(g/m^2-s per kg/m^3	m^3/kg	ug/m^3	ug/m3
EPA Default (EPA, 1996)	90.8	1.3E+09	7.6E-01	1E-04
Landau Associates (2003c)	---	4.6E+09	2.2E-01	2E-05
California Screening Value	38.5	5.6E+08	1.8E+00	2E-04
Eastern WA (Using values for Boise ID)				
0.5 acre	69.1	1.0E+09	1.0E+00	1E-04
5 acre	46.57	6.8E+08	1.5E+00	2E-04
10 acre	41.87	6.1E+08	1.6E+00	2E-04
30 acre	35.75	5.2E+08	1.9E+00	2E-04
Western WA (Using values for Seattle)				
0.5 acre	82.72	1.2E+09	8.3E-01	1E-04
5 acre	55.66	8.1E+08	1.2E+00	1E-04
10 acre	50.09	7.3E+08	1.4E+00	1E-04
30 acre	42.86	6.2E+08	1.6E+00	2E-04

[39] Q/C values obtained from Exhibit 11 of Soil Screening Guidance: User's Guide published by EPA's Office of Solid Waste and Emergency Response in July 1996 (Publication 93355.4-23)

Arsenic Exposure from Consumption of Homegrown Vegetables

Question #7: In evaluating arsenic-contaminated soils, Ecology did not quantify potential exposures resulting from the uptake of arsenic into homegrown vegetables due to uncertainties associated with estimating plant uptake. Is this approach consistent with current scientific information?

Ecology Approach and Rationale

Ecology has concluded that exposure resulting from the consumption of homegrown vegetables grown in arsenic-contaminated soils could represent an important exposure pathway. However, there are several sources uncertainty and variability that complicate efforts to estimate the amount of arsenic taken up by various plants and, consequently, Ecology did not quantify the potential exposures resulting from this pathway when establishing the working definition for arsenic-contaminated soils. This conclusion was reached after considering the following factors:

- <u>Results of Screening Level Analyses</u>: Screening level analysis performed using the methods and assumptions in the MTCA rule and EPA guidance documents predict that exposure via consumption of homegrown vegetables can represent an important exposure pathway representing 15 to 60% of overall exposure to arsenic-contaminated soils.
- <u>EPA Exposure Guidance and Site-Specific Assessments</u>: Site-specific exposure assessments prepared in accordance with EPA guidance documents have concluded that exposure via consumption of homegrown vegetables is a potentially important pathway. However, there are significant differences in approaches used to characterize potential exposures and how the results from these assessments are considered when selecting cleanup actions for arsenic-contaminated soils at federal Superfund sites.
- <u>Scientific Review Committees</u>: EPA found that consumption of homegrown vegetables could be an important pathway for exposure to arsenic contaminated soils. However, EPA decided not to combine exposure estimates for this pathway with exposure estimates for soil ingestion/dermal contact when making remedial action decisions because of the uncertainties in plant arsenic levels and the percentage of inorganic arsenic. In a recent review, a National Research Council (2005) subcommittee concluded that EPA's evaluation of soil-related human health risks at the Coeur d'Alene Superfund site was consistent with EPA guidance documents and current scientific information.
- <u>Uncertainty and Variability:</u> The point estimates developed using the methods and parameters in current EPA guidance documents appear to provide health conservative exposure estimates in that the point estimates generally fall at the upper end of simulated distributions that take into account the variability in individual exposure parameters. However, the degree of conservatism (as measured by where the point estimate falls within the simulated distribution) may be less for this pathway than other potential pathways (e.g. incidental soil and dust ingestion, dermal contact). Consequently, the screening analyses may underestimate the contribution of homegrown vegetables relative to other pathways

SAB Conclusions and/or Requests for Additional Information

The Science Advisory Board has not discussed this issue in the context of characterizing potential exposures to arsenic-contaminated soils. However, the Board concluded that this pathway could be a significant source of exposure to lead-contaminated soils.

Background Information

Potential exposure resulting from consumption of homegrown vegetables grown in arsenic-contaminated soils was estimated using the equations and parameters in EPA guidance materials (1996, 1997a,b,c, 2002a). The equation and parameters are shown in Figure 6.

The MTCA rule does not include methods and parameters for evaluating consumption of homegrown vegetables grown in arsenic-contaminated soils. Landau Associates (2003d) using the methods and parameters included in EPA guidance materials to estimate lifetime average daily doses (LADDs) and average daily doses (ADDs) for this pathway. The Landau analysis indicates that this pathway could be a significant contributor to exposure to arsenic-contaminated soils. NOTE: The estimated exposure from consumption of vegetables grown in contaminated soils is similar to the inorganic arsenic intake rates in U.S children estimated by Yost et al. (2004)[40].

Table 25: Comparison of Relative Contributions of Different Exposure Pathways to Estimates of Soil-Related Arsenic Exposure

	Soil Ingestion		Dermal Contact		Particulate		Home Grown Vegetables	
Evaluation	mg/kg/day	%	mg/kg/day	%	mg/kg/day	%	mg/kg/day	%
Landau (2003) - residential	1.0E-04	40%	2.2E-06	1%	4.2E-09	0%	1.5E-04	59%
Landau (2003) - schools	2.5E-05	94%	1.7E-06	6%	3.7E-10	0%	NA	0%
Ecology (2004) - residential	1.0E-04	79%	6.6E-06	5%	4.2E-09	0%	2.0E-05	16%
Ruston - residential	1.3E-04	58%	6.2E-06	3%	1.8E-06	1%	8.6E-05	39%
Vasquez Blvd/ I-70 - residential	1.0E-04	70%	3.0E-06	2%	2.0E-06	1%	3.8E-05	27%
Coeur d'Alene - residential	9.8E-05	60%	1.1E-05	7%	1.0E-07	0%	5.4E-05	33%

Site-specific exposure assessment prepared in accordance with EPA exposure guidance indicates that consumption of homegrown vegetables grown in contaminated soils could be an important exposure pathway. For example, exposure via this pathway was estimated to contribute to the overall exposure at the Coeur d' Alene Basin Superfund site (33%), Vasquez Boulevard/Interstate 70 Superfund site (27%) and the Ruston/North Tacoma Superfund site (39%). There are substantial differences in (1) the methods used to estimate exposure and (2) how EPA has used the results of those evaluations when making remedial action decisions.

- Coeur d'Alene: EPA's exposure estimates were based on arsenic concentrations measured in homegrown vegetables from homes in the area. However, EPA decided not to combine exposure estimates for this pathway with exposure estimates for soil ingestion/dermal contact when making remedial action decisions because of the uncertainties in plant arsenic levels and the percentage of inorganic arsenic. In a recent review, a National Research Council (2005) subcommittee concluded that

[40] Yost et al. (2004) estimated a mean childhood dietary inorganic arsenic intake of 3.2 ug/day with a range of 1.6 to 6.2 ug/day for the 10^{th} and 95^{th} percentile estimates, respectively. The Landau estimate corresponds to a daily intake of 2.4 ug/day (1.5 E-04 mg/kg/day x 16 kg = 2.4 ug/day).

EPA's evaluation of soil-related human health risks at the Coeur d'Alene Superfund site was consistent with EPA guidance documents and current scientific information.

- Ruston/North Tacoma: Glass and SAIC (1992) estimated exposure resulting from this pathway by predicting plant arsenic concentrations using plant uptake factors developing from studies in the Puget Sound area. On a conceptual basis, this approach is similar to the approach used by Landau Associates (2003c). EPA appears to have combined exposure estimates for this pathway with soil ingestion/dermal contact exposure estimates when making decisions on remedial action decisions.
- Vasquez Boulevard/Interstate 70: EPA's exposure estimates were based on arsenic concentrations measured in homegrown vegetables from homes in the area. EPA appears to have combined exposure estimates for this pathway with soil ingestion/dermal contact exposure estimates when making decisions on remedial action decisions.

Figure 6
Exposure Model for Ingestion of Vegetables and Fruits

$$LADD / ADD = \frac{C_s \cdot \left(\sum (BF * FWF * CR * F)\right) \cdot SR \cdot AB1 \cdot EF \cdot ED}{AT}$$

Where:

LADD = Lifetime average daily dose (mg/[kg-d])
ADD = Average daily dose (mg/[kg·d])
ABW = Child body weight (kg)
AB1 = Gastrointestinal absorption factor (unitless)
AT = Averaging time (yr)
BF = Plant-soil bioaccumulation factor for fruits/vegetables ([mg/kg]/[mg/kg])
CR = Consumption rate for homegrown fruits/vegetables (kg//kg/d)
C_s = Contaminant concentration in soil (mg/kg)
EF = Exposure frequency (unitless)
ED = Exposure duration (yr)
F = Fraction of contaminated fruits and vegetables consumed (unitless)
FWF = Fresh-to-dry weight conversion (unitless)
SR = Ratio of inorganic arsenic to total arsenic (unitless)

Parameter	Units	LADD	ADD
AB1	unitless	1.0	1.0
AT	yr	75	6
BF	mg/kg/mg/kg	Table 4.9	Table 4.9
CR	kg/day	Table 4.9	Table 4.9
C_s	mg/kg	7 – 500	7-500
EF	unitless	1	1
ED	yr	6	6
F	unitless	Table 4.9	Table 4.9
FWF	unitless	Table 4.9	Table 4.9
SR	unitless	0.5	0.5

Table 4-9: Exposure Parameters Used to Estimate Arsenic Exposure Resulting From Consumption of Homegrown Fruits and Vegetables

Parameter	Exposed Vegetables	Exposed Fruits	Root Vegetables
Plant –Soil Bioaccumulation Factor ((mg/kg)/(mg/kg))	0.011	0.002	0.008
Consumption Rate (kg/kg/day)	0.009	0.006	0.008
Dry-to-Wet Conversion (unitless)	0.085	0.15	0.085
Fraction Grown at Home (unitless)	0.42	0.33	0.17

There are several sources of uncertainty and variability that complicate the interpretation of the modeling results for this pathway.

The remaining portions of this section are not ready for prime time due to substantial uncertainty and variability in comparisons and evaluations. The materials will be provided at a later date.

Methods and Assumptions Used to Estimate Exposure

Questions #8: Are the methods, parameters and assumptions used to estimate exposure to arsenic-contaminated soils consistent with current scientific information?

Ecology Rationale

Ecology believes that the methods, parameters and assumptions used to estimate exposure to arsenic-contaminated soils are consistent with current scientific information. In reaching this conclusion, Ecology considered the following factors:

- Consistency with MTCA Regulatory Requirements: The methods, parameters and assumptions used to estimate exposure are consistent with the methods, parameters and assumptions used to establish soil cleanup levels under MTCA.
- Consistency with EPA Exposure Guidance and Site-Specific Assessments: The methods, parameters and assumptions used to characterize arsenic exposure are generally consistent with the methods, parameters and assumptions in EPA exposure guidance documents and site-specific assessments performed at sites with arsenic-contaminated soils.
- Conclusions/Findings of Scientific Review Panels: The MTCA Science Advisory Board has reviewed the methods and parameters in the MTCA rule and concluded that they are consistent with current scientific information. A recent National Research Council committee concluded that the exposure assessment for the Coeur de'Alene Superfund site was consistent with current scientific information. The methods, parameters and assumptions used by Ecology to characterize exposure to arsenic-contaminated soils are consistent with the procedures used to estimate exposure at the Coeur de' Alene site.
- Uncertainty and Variability: Yes.

SAB Conclusions and/or Requests for Additional Information

The Board has not discussed this issue with respect to arsenic-contaminated soils.

Background Information

Ecology believes that the methods, parameters and assumptions used to estimate exposure to arsenic-contaminated soils are consistent with current scientific information. In reaching this conclusion, Ecology considered the following factors:

- Consistency with MTCA Regulatory Requirements: Ecology believes that methods, parameters and assumptions used to characterize arsenic exposure are consistent with the MTCA Cleanup Regulation. Ecology and other individual and organizations have used the MTCA methods to establish soil cleanup levels at numerous cleanup sites in Washington.
- Consistency with EPA Exposure Guidance and Site-Specific Assessments: Ecology believes the methods, parameters and assumptions used to characterize arsenic exposure are generally consistent with EPA exposure guidance documents and site-specific assessments performed at sites with arsenic-contaminated soils. Table __ compares the

exposure parameters and exposure estimates prepared for two EPA Superfund sites using the Exposure Factors Handbook (EPA, 1997) with those specified in the MTCA rule.

- The default MTCA exposure parameters used to predict exposure via soil ingestion and dermal contact are consistent with parameters used by EPA to prepare site-specific exposure assessment. Differences in exposure estimates are largely driven by the choice of GI absorption factor with site-specific values (0.42 and 0.6) being lower than the MTCA default value (1.0)
- The residential LADD estimate developed using the MTCA equations is higher than the LADD estimates developed using EPA exposure guidance if a six (6) year child exposure duration is used to estimate the LADD.
- The residential LADD estimate developed using the MTCA equations is similar to the LADD estimates developed using EPA exposure guidance based on an integrated child/adult exposure (30 year exposure duration).
- Average daily dose (ADD) estimates based on the MTCA methods and assumption are higher than CTE and RME estimates prepared in accordance with EPA guidance. [Not shown in comparison table]

Comparison of Exposure Parameters and Lifetime Average Daily Dose (LADD) Estimates

			Vasquez Blvd/I-70 Site (CO)				**Coeur d'Alene Basin**				**MTCA (home)**	**MTCA (school & child care)**
			CTE - Child	**CTE - Adult**	**RME- Child**	**RME - Adult**	**CTE - Child**	**CTE- Child/ Adult**	**RME - Child**	**RME- Child/ Adult**		
Soil concentration	C	**mg/kg**	100	100	100	100	100	100	100	100	100	100
Soil ingestion rate	SIR	**mg/day**	100	50	200	100	100	50	200	100	200	200
GI abs. fraction	AB1	**unitless**	0.42	0.42	0.42	0.42	0.6	0.6	0.6	0.6	1.0	1.0
Skin surface area	SA	**cm2**	NA	NA	NA	NA	2,200	2,500	2,200	2,500	2,200	2,200
Adherence factor	AF	**mg/cm^2-day**	NA	NA	NA	NA	0.2	0.1	0.2	0.1	0.2	0.2
Dermal abs.fraction	ABS	**unitless**	NA	NA	NA	NA	0.03	0.03	0.03	0.03	0.03	0.03
Exposure frequency	EF	**unitless**	0.65	0.65	1	1	0.7	0.7	1	1	1	0.7
Exposure duration	ED	**years**	2	7	6	24	2	7	6	24	6	6
Body Weight	BW	**kg**	15	70	15	70	15	70	15	70	16	16
Averaging Time	AT	**years**	70	70	70	70	70	70	70	70	75	75
Unit Conv. Factor	UCF	**mg/kg**	1.0E06	1.0E06	1.0E06	1.0E06	1.0E06	1.0E06	1.0E06	1.0E06	1.0E06	1.0E06
Age-Group LADD	**mg/kg/day**		5.2E-06	2.0E-06	4.8E-05	2.1E-05	9.8E-06	3.8E-06	7.6E-05	3.3E-05	**1.1E-04**	**7.5E-05**
Cumulative LADD	**mg/kg/day**		**7.2E-06**		**6.9E-05**		**1.4E-05**		**1.1E-04**		**1.1E-04**	**7.5E-05**

- Conclusions/Findings of Scientific Review Panels: The MTCA Science Advisory Board reviewed the methods and parameters in the MTCA rule and concluded that they were consistent with current scientific information available at the time of rule adoption. A recent National Research Council (2005) committee reviewed the methods used by the Environmental Protection Agency to characterize the health and ecological risks at the Coeur d'Alene Basin Superfund site. Although issues dealing with lead-contaminated soils were the primary focus of the review, the NRC committee concluded that the exposure assessment for arsenic-contaminated soils was consistent with EPA guidance and current scientific information. The methods, parameters and assumptions used by Ecology to characterize exposure to arsenic-contaminated soils are consistent with the procedures used at the Coeur de' Alene site.

- Uncertainty and Variability: There are a number of sources of uncertainty and variability that complicate efforts to develop and interpret exposure estimates. The MTCA procedures are designed to produce a health-conservative estimate of exposure. However, the assumptions used to estimate exposures may either underestimate or overestimate soil-related exposures for particular sites.

Factors Contributing to Uncertainty and Variability in Exposure Estimates		
Factors or assumptions that would tend to underestimate exposure	**Factors or assumptions that might overestimate or underestimate exposure**	**Factors or assumptions that would tend to overestimate exposure**
• Exposure estimates based on measurements of 2 mm size fraction. • Inhalation pathway identified as a minor contributor to overall exposure. • Not combining exposure estimates for homegrown vegetables with exposure estimates for direct contact. • Use of 6 year duration of exposure to estimate LADD. • Soil ingestion rates do not explicitly address pica behavior.	• Variability in soil concentrations. • Default assumptions for soil ingestion rate. • Assumptions regarding dermal absorption of soil-bound arsenic. • Assumptions on the relationship between arsenic concentrations in soils and dust. • Assumptions on dermal adherence factors. • Assumptions on plant uptake and homegrown vegetable consumption rates. • Default assumptions on averaging time and body weight for LADD estimates. • Consideration of exposure from multiple properties.	• Default assumptions for GI absorption factor. • Default assumptions for frequency of exposure. • Methodology used to predict average daily dose for purposes of comparison with reference doses. • Soil aging effect and impacts on bioavailability (particularly for predicting exposure from dermal contact and plant uptake) • Assumption that all of the arsenic present in homegrown vegetables is in the inorganic form. • Relationship between arsenic concentrations in yard and garden soils.

Recommendations on Data Collection and Evaluations

Question #11: Are there specific information collection and analysis activities that the Board recommends Ecology undertake to address data gaps and uncertainties in the information used to estimate exposure and health risks associated with arsenic-contaminated soils?

Discussion

The Board provided several recommendations for future information collection and evaluation related to lead-contaminated soils. Several of the recommendations may be equally applicable to arsenic-contaminated soils.

- Collect and evaluate information on the variability in blood lead concentration in Washington children and the various risk factors that influence blood lead concentrations. The Board noted that current blood lead sampling is based on non-random sampling which prevents meaningful extrapolation to the general population.
- Collect and evaluate information on soil lead concentrations in Washington in order to better characterize the variability in lead concentrations and use that information when designing property-specific sampling efforts. The Board stated that it is important to identify factors that influence variability in soil concentrations.
- Collect and evaluate existing information on lead concentrations in vegetables grown in Washington. The Board noted this is a particular concern with respect to evaluating health risks associated with the consumption of commercial crops grown in area-wide contamination zones. The Board observed that use of data on lead concentrations in food from national surveys may not be appropriate for characterizing health risks in such situations.
- Collect and evaluate information on the relationship between soil pH levels and other factors that might influence the potential for lead in surface soils to migrate into underlying groundwater aquifers including considering various forms of lead. Stan Peterson suggested that Ecology consider the bioavailability of various forms of lead (and arsenic) as the science becomes available.
- Periodically review, evaluate and, as appropriate, revise the Method A soil cleanup level for lead based on scientific information on adverse health effects associated with blood lead concentrations below 10 ug/dL.
- Collect and evaluate information on soil lead concentrations along roads in Washington.
- The Board noted that outcome of the eventual SAB discussion about ecological impacts associated with arsenic- and lead-contaminated soils may point to additional data needs.

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